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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Local No. 1 Health Fund, and Plan of Benefits for the Local No. 1 Health Fund, individually and on behalf of all others similarly situated, Plaintiffs, v. Eli Lilly and Company, Novo Nordisk Inc., and Sanofi-Aventis U.S. LLC, CaremarkPCS Health, LLC d/b/a CVS Caremark, Caremark LLC, Caremark Rx LLC, Express Scripts, Inc., Medco Health Solutions, Inc., ESI Mail Pharmacy Services, Inc., Express Scripts Pharmacy, Inc., and OptumRx, Inc. Defendants	Case No. JURY TRIAL DEMANDED

DIRECT PURCHASER CLASS ACTION COMPLAINT

DIRECT PURCHASER CLASS ACTION COMPLAINT

Plaintiffs Local No. 1 Health Fund ("Local 1 Health Fund"), and Plan of Benefits for the Local No. 1 Health Fund ("Local 1 Health Fund Plan") (together "Plaintiffs" or "Local 1"), individually and on behalf of all others similarly situated direct purchasers, allege the following based upon personal knowledge as to Local 1, the investigation of counsel, and information and belief.

I. NATURE OF THE CASE

1. Local 1 brings this proposed class action against defendant drug manufacturers Eli Lilly and Company ("Eli Lilly"), Novo Nordisk Inc. ("Novo"), and Sanofi-Aventis U.S. LLC ("Sanofi") (together, "Manufacturer Defendants") and pharmacy benefit manager defendants CaremarkPCS Health, LLC d/b/a CVS Caremark, Caremark LLC, Caremark Rx LLC, Express Scripts, Inc., Medco Health Solutions, Inc., ESI Mail Pharmacy Services, Inc., Express Scripts Pharmacy, Inc., and OptumRx, Inc. (together, "PBM Defendants"), relating to Defendants' fraudulent and unlawful scheme to artificially inflate the prices of certain insulin medications in the United States.[1]

2. Local 1 brings this class action to recover for the injuries caused by Defendants' unlawful practices in connection with the marketing, pricing, sale, and

[1] PBM Defendants and the Manufacturer Defendants are jointly referred to herein as "Defendants."

distribution of the long-acting analog insulins, Lantus® ("Lantus") and Levemir® ("Levemir"), and the rapid-acting analog insulins, NovoLog® ("NovoLog") and Humalog® ("Humalog") that began in 2009 and have continued to the present date. NovoLog, Humalog, Lantus and Levemir are collectively referred to herein as the "Insulin Drugs."

3. Diabetes is an epidemic in the United States. As of 2022, an estimated 37.3 million people in the United States—11.3% of the population—were living with Type 1 or Type 2 diabetes.[2]

4. Manufacturer Defendants collectively manufacture approximately 90% of the Insulin Drugs sold in the United States.

5. *First*, in violation of Section 2(c) of the Robinson-Patman Act, 15 U.S.C. § 13(c), the PBM Defendants solicited and the Manufacturer Defendants paid bribes and kickbacks not for services rendered, but to induce the PBM Defendants to include the Insulin Drugs on health benefit providers' "formularies." These formularies are controlled by the PBM Defendants and determine whether and to what extent the nation's health care insurers and other health care third-party payors (collectively referred to herein as "TPPs") pay for their insureds to receive life-sustaining insulins.

[2] *See* https://www.cdc.gov/diabetes/data/statistics-report/index.html.

6. *Second,* Defendants operated and/or conspired to operate one or more enterprises that secured the sale of the Insulin Drugs at artificially inflated prices through a pattern of racketeering activity that affected interstate commerce as defined in 18 U.S.C. § 1961(1) in violation of the provisions of the Racketeer Influenced and Corrupt Organization Act ("RICO"), 18 U.S.C. § 1962(c), (d). Such racketeering activities included, among other things:

a. Publishing artificially increased prices and systematically making false representations through the U.S. mail and interstate wires that the operation of the formulary system (controlled by the PBM Defendants) and the pricing mechanism for the Insulin Drugs used by the Manufacturer Defendants operated to reduce the cost of analog insulin to purchasers when, in reality, Defendants were systematically acting to increase prices of the Insulin Drugs by engaging in kickback schemes, all in violation of 18 U.S.C. §§ 1341 and 1343 (*see* 18 U.S.C. § 1961(1)(B));

b. Falsely and fraudulently representing to the TPP clients of the PBM Defendants, to Class members, and to the public through the U.S. mail and interstate wires that the "Administrative Fees" or "Manufacturer Administrative Fees" charged by the PBM Defendants to the Manufacturer Defendants as a condition to formulary placement of the

Insulin Drugs were, in words or substance, "for administrative services performed by Pharmacy Benefit Manager in relation to the processing, invoicing for or collection of any Rebates" when those services are already performed by the PBM Defendants and paid for by the TPP clients of the PBM Defendants pursuant to the contracts between the TPP clients and the PBM Defendants that represent them, all in violation of 18 U.S.C. § 1341 (*see* U.S.C. § 1961(1)(B));

c. Engaging in commercial bribery chargeable as such and punishable by imprisonment for more than one year under state law (*see* 18 U.S.C. § 1961(1)(A));

d. Payment of kickbacks by the Manufacturer Defendants, and the receipt of kickbacks by the PBM Defendants who provide ERISA benefit plan services to the employer sponsored health benefit plans (i.e., each an "employee welfare benefit plan" under 29 U.S.C. § 1002(1)) that provide health coverage for over 180 million American residents with the intention of influencing the choice of analog insulin to include in the benefit plan formularies that determine whether and to what extent a particular insulin is available to patients on favorable terms, all in direct violation of 18 U.S.C. § 1954 (*see* 18 U.S.C. § 1961(1)(B));

e. In violation of 18 U.S.C. §1957, knowingly engaging in monetary transactions in property of a value greater than $10,000 derived from unlawful activity consisting of violations of the Federal Antikickback Statute ("AKS") taking place in the United States or its territories and affecting interstate commerce (*see* 18 U.S.C. § 1961(1)(B)). Section 1957 provides that it is a federal crime to "knowingly engage[ ] … in a monetary transaction in criminally derived property of a value greater than $10,000 and is derived from specified unlawful activity." For this purpose:

- The term "monetary transaction" means a "deposit, withdrawal, transfer, or exchange, in or affecting interstate … commerce, of funds or a monetary instrument … by, through, or to a financial institution." 18 U.S.C. § 1957(f)(1).
- "Proceeds" means "any property derived from or obtained or retained, directly or indirectly, through some form of unlawful activity." 18 U.S.C. § 1957(f)(3) (citing 18 U.S.C. § 1956 (c)(9)).
- The term "specified unlawful activity" includes "any activity constituting an offense involving a Federal health care

offense." 18 U.S.C. § 1957(f)(3) (citing 18 U.S.C. § 1956 (c)(7)(F)).

- A "'Federal health care offense' means a violation of … section 1128B of the Social Security Act (42 U.S.C. § 1320a-7b)." 18 U.S.C. §24(a)(1).
- Subsection (b) of 42 U.S.C. § 1320a-7b prohibits any person from knowingly and willfully soliciting or receiving "any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind" in exchange for "recommending purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal health care program."
- For this purpose, a "Federal health care program" is defined as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government" or certain state health care plans funded or approved by the federal government; specifically, Medicaid under subtitle XIX of title 42, block grants for maternal and

child care under subtitle V of title 42, and block grants for social services under subtitle XX.A of title 42. *See* 42 U.S.C. § 1320a-7b(f) (citing 42 U.S.C. § 1320a-7(h)).

f. Engaging in commercial bribery in violation of the Travel Act, 18 U.S.C. § 1952 (*see* 18 U.S.C. § 1961(1)(B)), which:

i. Makes it a crime to use the mail or any facility in interstate commerce to commit "bribery … in violation of the laws of the State in which they are committed;"

ii. Makes it a crime to engage in "bribery … in violation of the laws … of the United States," with 18 U.S.C.§ 666(a), (b) outlawing bribery by making it a felony for an agent of an organization or government "to corruptly solicit[ ] or demand[ ] for the benefit of any person, or accept[ ] or agree[ ] to accept, anything of value from any person, intending to be influenced or rewarded in connection with any business, transaction, or series of transactions of such organization … involving anything of value of $5,000 or more" where the "organization … receives, in any one year period, benefits in excess of $10,000 under a Federal program involving a grant, contract, subsidy, loan, guarantee, insurance, or other form of Federal assistance; and

iii. Prohibits carrying on of activities in violation of 18 U.S.C. § 1957 and, therefore, the AKS as set forth in greater detail in subparagraph "e" of this paragraph.

II. Jurisdiction and Venue

7. This Court has subject matter jurisdiction over Plaintiffs' Section 2(c) Robinson-Patman claims pursuant to 28 U.S.C. §§ 1331 and 1337 because Plaintiffs' claims arise under federal antitrust law.

8. The Court has subject matter jurisdiction over Plaintiffs' RICO claims pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1964(c) because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962.

9. This District Court is presiding over a multi-district litigation commenced by direct purchasers, indirect purchasers, direct action plaintiffs, and others who have sued certain defendants for perpetrating their unlawful scheme to inflate insulin prices. *See In re Insulin Pricing Litig*., No. 2:23-md-3080-BRM-RLS (D.N.J.).

10. From January 1, 2009 to the present (the "Class Period") the Manufacturer Defendants sold, shipped, and paid kickbacks in connection with the Insulin Drugs, the PBM Defendants received kickbacks in connection with such sales, and the PBM Defendants sold and shipped Insulin Drugs via their mail-order pharmacies, in a continuous and uninterrupted flow of interstate commerce which included sales of the Insulin Drugs in this District and throughout the United States and kickbacks from the proceeds of such sales. Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District.

11. This Court has personal jurisdiction over each Defendant because, *inter alia*: (a) certain Defendants maintain their principal places of business in this

District; (b) Defendants transacted business throughout the United States, including in this District; (c) Defendants participated in the purchase, sale, and distribution of the Insulin Drugs throughout the United States, including in this District; (d) Defendants had and maintained substantial contacts with the United States, including in this District; (e) Defendants were members of unlawful enterprises designed to artificially inflate the prices for the Insulin Drugs by demanding and receiving substantial kickbacks; and/or (f) those enterprises and kickbacks were directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

12. Venue is proper in this District pursuant to 18 U.S.C. § 1965, 15 U.S.C. §§ 15 and 22, and 28 U.S.C. §§ 1391(b) and (c), because during the Class Period, Defendants: (a) resided in this District; (b) transacted business in the United States, including in this District; (c) were found in this District; and/or (d) maintained agents in this District.

III. The Parties

A. Plaintiffs

13. Plaintiff Local No. 1 Health Fund ("Local 1 Health Fund") is a multi-employer plan whose stated purpose is to provide health benefits to eligible members and their dependents. Local 1 Health Fund is maintained and administered in accordance with and pursuant to the provisions of Section 302(c)(5) of the National

Labor Relations Act. Local 1 Health Fund maintains its principal place of business in Downers Grove, Illinois.

14. Plaintiff Plan of Benefits for the Local No. 1 Health Fund and associated plans ("Local 1 Health Fund Plan") is the health benefits plan that the Local 1 Health Fund has sponsored from at least 2008 through the present. The Local 1 Health Fund Plan is based in and administered from Downers Grove, Illinois. The Local 1 Health Fund provides its eligible members and their dependents with healthcare benefits through the Local 1 Health Fund Plan, a self-insured healthcare plan. For the year 2020, approximately 6,000 eligible members and their dependents participated in the Local 1 Health Fund Plan. Local 1 contracts directly with one or more of the Defendants to purchase Insulin Drugs.

15. Between 2009 and the present, Local 1 paid for NovoLog, Humalog, Lantus and Levemir purchased directly from Express Scripts and Caremark via these PBMs' mail-order pharmacies. In connection with those direct purchases, Local 1 paid more for Insulin Drugs than it otherwise would have paid had Defendants not engaged in the conduct complained of in this Complaint. Local 1 has standing and has sustained antitrust injury.

B. Defendants

16. Defendant Novo is a Delaware corporation with its principal place of business located at 800 Scudders Mill Road, Plainsboro, New Jersey. Novo is one

of the largest manufacturers of insulin drugs in the United States. During the Class Period, Novo manufactured and sold Levemir and NovoLog to purchasers in this District and throughout the United States.

17. Defendant Eli Lilly is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana. During the Class Period, Eli Lilly manufactured and sold Humalog to purchasers in this District and throughout the United States.

18. Defendant Sanofi is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey. During the Class Period, Sanofi manufactured and sold Lantus to purchasers in this District and throughout the United States.

19. Defendant CaremarkPCS Health, LLC conducts business as "CVS Caremark." CaremarkPCS Health, LLC is a Delaware limited liability corporation and is headquartered at One CVS Drive, Woonsocket, Rhode Island. CaremarkPCS Health, LLC provides pharmacy benefit management services to various health insurers and other third-party payors (collectively "TPPs"). CaremarkPCS Health, LLC is a wholly owned subsidiary of CVS Health Corporation.

20. Defendant Caremark LLC is a California limited liability company with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island. During the relevant time period, Caremark LLC provided pharmacy

benefit management services and mail-order pharmacy services to various TPPs, including Local 1. Caremark LLC is a wholly owned subsidiary of CVS Health Corporation.

21. Defendant Caremark Rx LLC is a Delaware limited liability company with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island. During the relevant time period, Caremark Rx LLC provided pharmacy benefit management services and mail-order pharmacy services to various TPPs, including Local 1. Caremark Rx, LLC is a wholly owned subsidiary of CVS Health Corporation.

22. CaremarkPCS Health, LLC; Caremark LLC; and Caremark Rx LLC are collectively referred to herein as "CVS Caremark."

23. Defendant Express Scripts, Inc. is a Delaware corporation with its principal place of business located at 1 Express Way, St. Louis, Missouri. Express Scripts, Inc. is a PBM and, as such, provides pharmacy benefit management services to various health insurers and other TPPs. Defendant Express Scripts, Inc. is a subsidiary of Evernorth Health, Inc ("Evernorth").

24. Defendant Medco Health Solutions, Inc. is a Delaware corporation with its principal place of business located at 100 Parsons Pond Road, Franklin Lakes, New Jersey. Medco Health Solutions, Inc. is a subsidiary of Evernorth. During the

relevant time period, Medco Health Solutions, Inc. provided pharmacy benefit management services and mail-order pharmacy services to various TPPs.

25. Defendant ESI Mail Pharmacy Services, Inc. is a Delaware corporation with its principal place of business located at 1 Express Way, St. Louis, Missouri. ESI Mail Pharmacy Services, Inc. is a wholly owned subsidiary of Evernorth. During the relevant time period, ESI Mail Pharmacy Services, Inc., provided mail-order pharmacy services to various TPPs, including Local 1.

26. Defendant Express Scripts Pharmacy, Inc. is a Delaware corporation with its principal place of business located at 1 Express Way, St. Louis, Missouri. Express Scripts Pharmacy, Inc. is a wholly owned subsidiary of Evernorth. During the relevant time period, Express Scripts Pharmacy, Inc., provided mail-order pharmacy services to various TPPs, including Local 1.

27. Express Scripts, Inc., Medco Health Solutions, Inc., ESI Mail Pharmacy Services, Inc., and Express Scripts Pharmacy, Inc., are collectively referred to herein as "Express Scripts."

28. Defendant OptumRx, Inc. ("Optum") is a California corporation with its principal place of business located at 2300 Main Street, Irvine, California. OptumRx provides pharmacy benefit management services and mail-order pharmacy service to various TPPs.

29. Defendants have engaged in the conduct alleged in this Complaint, and/or Defendants' officers, agents, employees, or representatives have engaged in the alleged conduct while actively involved in the management of Defendants' business and affairs and acting within the scope of their employment.

30. Upon information and belief, various other companies and individuals not named as defendants in this Complaint may have participated as co-conspirators in the violations alleged herein, and aided, abetted, performed acts, and made statements in furtherance of such conspiracy.

31. The acts alleged herein that were done by each of the co-conspirators were fully authorized by each of those co-conspirators, or were ordered, or committed by duly-authorized officers, managers, agents, employees, or representatives of each co-conspirator while actively engaged in the management, direction, or control of its affairs.

IV. Factual Background

A. The Prevalence of Diabetes in the United States.

32. Diabetes is an epidemic in the United States. As of 2022, an estimated 37.3 million people in the United States—11.3% of the population—were living with Type 1 or Type 2 diabetes.[3]

[3] *See* https://www.cdc.gov/diabetes/data/statistics-report/index.html.

33. Diabetes occurs in patients who have a lack of insulin production or an inability to respond to insulin.

34. Insulin, which regulates metabolic processes in the body, is created by the pancreas. Insulin enables cells in the body to absorb glucose from the blood. Glucose serves as energy for cells or is converted to fat for storage. Insulin also regulates the breakdown of fat and protein.

35. There are two types of diabetes. "Type 1" diabetes occurs when the pancreas is damaged, resulting in a chronic condition in which the pancreas produces little or no insulin. In "Type 2" or "adult onset" diabetes there are primarily two interrelated problems at work: the pancreas does not produce enough insulin and cells respond poorly to insulin and take in less sugar, resulting in excess sugar in the circulating blood stream.

B. The Development and Importance of Analog Insulins.

36. The primary goal in the treatment of diabetes is the management of the heightened blood sugar level that results from the disease. A necessary treatment for Type 1 diabetes and a common treatment for Type 2 diabetes is insulin therapy.

37. Analog insulins are a sub-group of human insulin. Analog insulins are laboratory grown, but genetically altered to create either a more rapid-acting or more uniformly acting form of insulin.

38. There are primarily two types of analog insulin: rapid-acting insulin and long-acting insulin. Each is used in the management of diabetes, with all insulin-dependent patients receiving long-acting insulin and many insulin-dependent patients also receiving rapid-acting or mixed insulin.

39. Doctors and patients prefer analog insulins because they more closely mimic the way the human body naturally absorbs insulin released by the pancreas. As a result, analog insulins provide increased treatment options.

40. The American Diabetes Association (the "ADA") publishes standards of medical care in diabetes.[4] The ADA recommends insulin analogs for both Type 1 and Type 2 diabetes patients.

41. Due to the advantages of analog insulin, analog insulin dominates the insulin markets for both long-acting analog insulins and rapid-acting analog insulins and sales of natural human insulin products, such as Novo's Novolin and Eli Lilly's Humulin, have dropped drastically.

[4] *See* American Diabetes Association Standards of Medical Care in Diabetes – 2017, THE JOURNAL OF CLINICAL AND APPLIED RESEARCH AND EDUCATION, DIABETES CARE®, https://professional.diabetes.org/files/media/dc_40_s1_final.pdf.

42. IMS data[5] for 2016 shows that the top-selling insulins in the United States were analogs: Lantus ($8.87 billion); Levemir ($1.82 billion); NovoLog ($5.86 billion); and Humalog ($5.88 billion).

C. Analog Insulin Brands are Therapeutically Interchangeable.

43. The long-acting analog insulins Lantus and Levemir are very similar drugs with few differences that impact treatment. They are generally considered to be therapeutically interchangeable.

44. Both Lantus and Levemir are available in vial and cartridge delivery forms and are suitable for once-daily administration.

45. Likewise, the rapid-acting insulins NovoLog and Humalog appear to have identical effects in diabetes patients. Thus, NovoLog and Humalog also are considered therapeutically interchangeable.

46. Studies show that there is no meaningful difference in the effectiveness of Levemir versus Lantus, or Humalog versus NovoLog. The FDA has stated that, in certain circumstances, one brand of rapid-acting insulin may be substituted for

[5] IMS data is provided by IMS Health, Inc. ("IMS Health") (n/k/a IQVIA). IMS Health collects pricing data from retail pharmacies, including independents, chains, and pharmacies within food stores or mass merchandisers.

another brand of rapid-acting insulin and that one brand of long-acting insulin may be substituted for another brand of long-acting insulin.[6]

47. Generally, diabetes patients can easily switch insulin brands. In most states, a physician does not need to write a new prescription for a patient to switch insulin brands.

D. The Participants in the Distribution and Sale of Pharmaceuticals.

48. The critical players in the prescription drug industry include drug companies, drug distributors, pharmacies, Third-Party Payors ("TPPs"), and Pharmacy Benefit Managers ("PBMs") as described below.

49. **Drug Companies.** Drug companies, also known as drug manufacturers, own the rights to manufacture and market drugs. Drug companies typically own or contract with facilities that manufacture drugs and then sell their products directly to FDA-registered drug distributors, certain large pharmacies or pharmacy outlets, and certain TPPs.

50. Drug companies set the price to be paid by any distributor or TPP purchasing from it directly by tying or tethering the price to what is referred to in the industry as the "Wholesale Acquisition Cost" or "WAC." Drug companies contract

[6] *See* "Information Regarding Insulin Storage and Switching Between Products in an Emergency," https://www.fda.gov/drugs/emergencypreparedness/ucm085213.htm.

directly with PBMs and sometimes TPPs to establish rebate agreements for products purchased and/or claims processed. Those rebate agreements are also tied to WAC. Drug companies, such as the Manufacturer Defendants, typically send its Direct Purchasers notifications regarding new Direct Purchaser Prices via the U.S. mail, electronic mail, or interstate wires.

51. **Drug Distributors.** FDA-registered drug distributors take possession of the drugs they purchase from drug companies and typically distribute them to pharmacies. In limited instances, drug distributors may also distribute the drugs to certain TPPs.

52. **Pharmacies.** Pharmacies are retailers and take the form of either traditional brick-and-mortar pharmacies or mail-order pharmacies. Pharmacies purchase drugs from drug companies or from drug distributors and sell those drugs to consumers and TPPs on behalf of consumers.

53. **Third Party Payors.** "Third Party Payors" or "TPPs" typically fall into three groups as follows:

- *Employee Welfare Benefit Plans*. Over 54% of the approximately 326 million individuals residing in the United States receive health insurance, including prescription drug benefits, pursuant to employer created, sponsored, and/or funded private health insurance.[7] These insurance arrangements are Employee Welfare Benefit Plans within the meaning of Section 1002(1) of the Employee Retirement Income Security Act, 29 U.S.C. § 1002(1).

[7] Congressional Research Service, *U.S. Health Care Coverage and Spending* (Apr. 1, 2022), https://sgp.fas.org/crs/misc/IF10830.pdf.

- *Federal Government Plans.* The federal government has established, funded, and administered individually and/or with the assistance of state governments, private managed care organizations, and/or PBMs a variety of programs that are responsible to fund the payment of prescription drug benefits, including Part D of Medicare, Medicaid, CHAMPVA, VA programs, and the like. Roughly 40% of the nation's population receives medical benefits, including prescription medication benefits, through these federal government programs.[8]

- Private Insurance and the Affordable Care Act. Approximately ten percent of the population receives prescription drug coverage through private insurance, most of which is purchased on or through the exchanges created by the Patient Protection and Affordable Care Act ("ACA"), 42 U.S.C. § 18001, et. seq.[9] Annually, the federal government provides over 50 billion dollars in subsidies to purchase private insurance on the ACA exchanges.[10]

54. TPPs make payments to pharmacies (both traditional brick-and-mortar and mail-order) for the cost of prescription drug benefits for their insureds and other covered individuals, less applicable co-pays and deductibles. Depending upon the drug and individual entity policies, TPPs can purchase drugs directly from either drug companies, drug distributors, brick-and-mortar pharmacies, mail-order pharmacies or a mixture of any of these.

55. **Pharmacy Benefit Managers**. PBMs are hired by TPPs to perform some or all of these tasks: (a) administer the terms of the prescription drugs benefits

[8] *Id*.

[9] *Id*.

[10] Congress of the United States, Congressional Budget Office, *Federal Health Insurance Subsidies* (2019).

that the TPPs are obligated to provide under the applicable contracts of insurance and/or applicable statutory/regulatory schemes; (b) pay on behalf of the applicable TPPs the amount owed to pharmacies by those TPPs for prescription medications dispensed to individuals insured or otherwise covered by the applicable TPP; (c) manage prescription billing; (d) effectuate financial and contractual arrangements between and among drug companies, pharmacies, and health benefit providers; and (e) provide mail-order services. Not all TPPs utilize PBMs for these functions but may instead contract with the Manufacturer directly in order to avoid the PBM middleman. PBMs contract with Drug Companies separate and apart from the TPPs to perform these services on behalf of the Drug Company.

56. PBMs also create networks of pharmacies. These networks can include PBM purchased pharmacies, PBM consolidated pharmacies, PBM affiliated retail pharmacies, and PBM mail-order pharmacies (e.g., OptumRx and Caremark Rx LLC). "A PBM that owns a pharmacy (whether retail or mail) is considered vertically integrated" within the pharmaceutical distribution chain[11] PBMs negotiate with these same pharmacies to set the amount those pharmacies will receive from PBM clients—TPPs. These PBM pharmacies (retail and mail-order) purchase

[11] Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (August 2025) at xv.

directly from pharmaceutical manufacturers or drug distributors,[12] take possession of the drug products, and sell the products directly to consumers and TPPs.

57. PBMs are in a position of superior knowledge and special expertise regarding the administration of prescription drug benefits and market their superior knowledge and special skills as a means of lowering costs for their TPP clients. "Due to Defendants' semblance of size and power, and their promise of mitzvah, plan sponsors presuppose and rely upon Defendants to be better than they at the management and cost-reduction of pharmacy benefits." *In re Express Scripts, Inc., PBM Litig.,* No. 05-md-01672-SNL, 2008 WL 2952787, at *3 (E.D. Mo. July 30, 2008). Given this "invited reliance" on the special expertise and skill of PBMs, they owe a duty of loyalty to their TPP clients in connection with the management of their respective pharmacy benefit plans, the development of formularies as described below, and the negotiation of drug prices with manufacturers.

E. The Power of PBMs.

58. PBMs have expanded from pharmacy claims processing to a business model that forces drug companies to engage in price negotiation in several drug categories. PBMs typically select one brand among several brand drugs in a therapeutic class as the "preferred" choice and then negotiate payments from that manufacturer called "rebates" and "administrative fees." So long as all of these

[12] *Id.* at 4.

rebates and administrative fees are passed back to the client, this rebate system could lower the net cost of that brand to TPPs.[13]

59. PBM Defendants reported revenues of more than $400 billion in 2022. Because increased size gives an individual PBM increased negotiating leverage, there has been dramatic consolidation in the PBM industry during the past decade. As of 2022, the top three PBMs (the PBM Defendants) controlled approximately 80% of the PBM market.

60. One of the key functions that PBMs perform for their clients is to negotiate supposed "rebates" with drug companies. However, rather than negotiating agreements with drug companies separately and individually for each of their TPP clients, PBMs typically are able to use their combined clout to negotiate a master agreement on behalf of all their clients. As a result, in the world of drug price negotiation, market power is most highly concentrated among PBMs, particularly the PBM Defendants, who have more negotiating leverage than any individual drug manufacturer or health benefit provider on either side of a transaction.

[13] *Prescription Drug Pricing: Pharmacy Benefit Managers*, Health Policy Brief Series, HealthAffairs, at 1 (Sept. 2017), https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/collectionitem/healthpolicybrief_178.pdf.

F. PBMs Control Drug Formularies

61. Formularies are a central tool that health benefit providers use in designating, managing, and publicly identifying the extent of the coverage and benefits they provide to their members. Because formulary coverage impacts how much a patient pays for a drug, formularies can be used to steer patients toward certain drugs over others, and that is one of the key purposes and functions of formulary design, implementation, and management.

62. While some PBM clients have formal, nominal control over the structure of the formularies they implement, they usually retain PBMs to develop and administer the formularies and give the PBM contractual authority to make day-to-day changes, unless the TPP takes the affirmative step of electing not to implement any such change. Here, the PBM Defendants have contractual authority to make day-to-day changes.

63. Most health benefit providers rely upon a PBM's formulary recommendations.[14] Indeed, the Express Scripts contract template provides that Express Scripts' additions and/or deletions to the formulary are automatically assumed to be adopted by the health plan sponsor, unless the sponsor takes the

[14] The PCMA — the PBM trade association — has testified to the Pennsylvania House of Representatives that even sophisticated health benefit providers, *i.e.*, insurers and health plans, rely on PBMs to manage their drug benefit. Letter from PCMA to Matthew E. Barker, Pennsylvania House of Representatives, House Comm. on Health (Aug. 28, 2013).

affirmative step of electing not to implement any such addition or deletion through the set-up form process.[15]

64. The PBM Defendants' contractual authority to make changes to the formulary list, combined with many clients' reliance on the PBM Defendants' formulary recommendations and decisions, gives the PBM Defendants substantial day-to-day control in managing their clients' formularies.

65. The PBM Defendants' control over formulary decisions is related to (and a necessary predicate of) their ability to negotiate manufacturer rebates, because manufacturers pay rebates based on the PBM Defendants' ability to deliver formulary placement for their drugs. This is because favorable formulary status is likely to increase (or at least maintain) a drug's usage and sales and formulary exclusion (or a downgrade in formulary position) is likely to reduce a drug's usage and sales. Manufacturer rebates are conditioned on a drug's formulary coverage.[16]

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[15] A well-known pharmacy-benefits consultant, David Dross, noted during a presentation that health plans "don't have clinicians on staff, they don't even question their PBM's formulary, much less design their own." *Employers Should 'Ask the Hard Questions' About PBM Formularies*, Health Business Daily (Dec. 19, 2014).

[16] As Cottingham & Butler (a national insurance broker) noted in a client presentation, PBMs have "unilateral control ... over formularies and tiering — driving greater profits for PBMs through rebates[.]" Nancy Daas, *Prescription Drug Plan Strategies*, Cottingham & Butler (2017), http://www.cottinghambutler.com/wp-content/uploads/2017/03/Prescription-Drug-Strategies.pdf.

66. In the past, PBMs generally devised and managed what are known as "open" formularies: formularies that offer varying degrees of plan coverage and benefits for virtually all available FDA-approved drugs. Consequently, with open formularies, drug companies compete to have their drugs placed by PBMs into the most favorable formulary tier possible.

67. Like open formularies, "closed" formularies provide tiered benefits, but unlike open formularies, they restrict the overall number of drugs that are entitled to receive any plan prescription drug benefit.

68. In the 2010s, PBMs, including the PBM Defendants, started shifting to making "closed" formularies the default choice for clients.[17] For example, in 2014, Express Scripts' national formulary was a closed formulary, and clients had to affirmatively opt-out of it.[18]

69. The Senate Finance Committee released a report on Jan. 14, 2021 detailing the "opaque" business dealings between drug manufacturers and pharmacy benefit managers, including the PBM Defendants, that led to the higher cost of

[17]Paul Lendner, *PBMs Just Say No to Some Drugs — But Not to Others*, Managed Care MAG.com (Apr. 2015), https://www.managedcaremag.com/archives/2015/4/pbms-just-say-no-some-drugs-not-others.

[18] *Id.*

insulin for the past 15 years.[19] The report pinned most of the blame on PBMs for encouraging drugmakers to raise their list price, or the Wholesale Acquisition Cost (WAC), to offer greater rebates and payments to PBMs and ensure that their product is included on the formulary "absent significant advances in the efficacy of the drugs." "These price increases appear to have been driven, in part, by tactics PBMs employed beginning in the early 2010s. At that time, PBMs began to more aggressively pit manufacturers against each other by implementing formulary exclusions in the insulin therapeutic class, which effectively stopped manufacturers from reaching large blocks of patients," the report states. "As a result, pharmaceutical manufacturers continued to raise WAC prices aggressively—increases that were often closely timed with price changes made by competitors (a practice that has been referred to as 'shadow pricing')."[20].

70. Over the last several years, the PBM Defendants have published annual lists of drug exclusions from formularies. PBMs' exclusion lists are closely analyzed by industry experts who understand that, through these lists, PBMs have the ability to drive health and insurance plan participants and beneficiaries to (or away from)

[19] Charles Grassley, Ron Wyder, US Senate Finance Committee, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,* at 6, 65 (Jan. 14, 2021), https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.

[20] *Id.* at 5.

specific drugs.[21] For example, in an August 2, 2016 article about CVS Caremark's and Express Scripts' 2017 formulary exclusions, *Barrons* stated:

> Make way for some waves. CVS Health (CVS) and Express Scripts (ESRX) have released their formulary exclusion list for 2017, which details which prescription drugs will not be covered by health plans.
>
> Why do we care? ... The coverage list determines whether millions of privately insured individuals can easily use an insurance co-payment to buy their prescriptions. If a drug is excluded, it can dramatically hobble sales.
>
> Thus, the formulary exclusion lists can be used as a tool by insurers and PBMs — leverage you might say — to negotiate with drug makers for better prices [for PBMs and plans].[22]

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[21] *See*, *e.g.*, Kevin McCaffrey, *PBMs Unveil 2017 Formularies, Retain Focus on Exclusions,* MM&M (Aug. 3, 2016), https://www.mmm-online.com/home/channel/payers-managed-markets/pbms-unveil-2017-formularies-retain-focus-on-exclusions/; Mark Lowery, *2016 Formulary Exclusions in 9 Key Areas*, Drug Topics: Voice of the Pharmacist (Aug. 11, 2015); Bruce Japsen, *PBMs Quietly Gain Leverage As Drug Makers Stumble On Price Hikes*, Forbes (Aug. 31, 2016), https://www.forbes.com/sites/brucejapsen/2016/08/31/pbms-quietly-gain-leverage-as-drug-makers-stumble-on-price-hikes/?sh=24507bc27ffa.

[22] Johanna Bennett, *CVS Health Takes "An Audacious Step" With 2017 Drug Formularies*, Barron's (Aug. 2, 2016), https://www.barrons.com/articles/cvs-health-takes-an-audacious-step-with-2017-drug-formularies-1470169569; *see also Excluded in 2016: These Drugs Are On the Outside Looking In*, Managed Care MAG.com (Sept. 10, 2015), https://www.managedcaremag.com/archives/2015/9/excluded-2016-these-drugs-are-outside-looking.

71. Placement on and exclusion from placement on the health benefit provider formularies is a major factor in the PBM Defendants' negotiations with drug companies (like the Manufacturer Defendants) for rebates and other types of payments. Indeed, the PCMA had admitted that "[i]n classes where several products may be considered therapeutically equivalent, PBMs can negotiate with drug companies for higher rebates."[23]

72. In April 2015, Express Scripts' Chief Medical Officer bragged to *Managed Care Magazine* that formulary exclusions "demonstrate that PBMs [can] move market share." He further touted that drug companies are "now convinced ... that [PBMs can] actually deliver market share when we [are] motivated to. So we went to the companies, and we told them, 'We're going to be pitting you all against each other. Who is going to give us the best price? If you give us the best price, we will move the market share to you. We will move it effectively. We'll exclude the other products.'"[24]

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[23] Thomas Beaton, *How Pharmacy Benefit Managers Lower Prescription Drug Prices,* Health Payer Intelligence (Sept. 19, 2017), https://healthpayerintelligence.com/news/how-pharmacy-benefit-managers-lower-prescription-drug-prices.

[24] Peter Wehrwein, *A Conversation With Steve Miller, MD: Come in and Talk With Us*, *Pharma*, Managed Care Mag. (April 2015), https://www.managedcaremag.com/archives/2015/4/conversation-steve-miller-md-come-and-talk-us-pharma/.

73. Similarly, a February 16, 2018 article in *STAT* (a well-known publication focused on the life sciences and pharmaceutical industries) states that PBMs — particularly the PBM Defendants — "[a]s the industry's heavyweights ... now have enormous power over the availability and pricing of essential medicines. Drug makers pay PBMs billions of dollars to ensure their products get preferred positions on formularies, drug lists used to determine which medicines are covered."[25]

74. Industry experts have further highlighted that the threat of formulary exclusion has yielded substantial payments from drug companies to PBMs. For example, Arthur Shinn of Pharmacy Consultants, LLC stated in a presentation that "[t]he exclusion strategy is a big rebate revenue generator."[26]

G. Federal and State Government Investigations of Insulin Pricing and "Rebates."

75. Various government entities have conducted investigations relating to the allegations described herein. On November 3, 2016, Senator Bernie Sanders and Representative Elijah E. Cummings sent correspondence to the Department of Justice ("DOJ") and the Federal Trade Commission ("FTC") requesting that the DOJ

[25] Casey Ross, *Washington is taking aim at drug industry middlemen. But can it break their grip on a captive market?* STAT (Feb. 16, 2018), https://www.statnews.com/2018/02/16/washington-pharmacy-benefit-managers/.

[26] *"As the Clock Ticks for Exclusion Opt-Ins, Payers Ponder Access, Disruption, Savings,"* Drug Benefit News, Vol. 15, Issue.

and the FTC "investigate whether pharmaceutical companies manufacturing insulin products have colluded or engaged in anticompetitive behavior in setting their drug prices."[27] The Congressmen noted, among other things, lockstep price increases for the Insulin Drugs,[28] which occurred at least 13 times since 2009.[29] News sources have similarly cited exponential price increases starting in 2009.[30]

76. On or about June 2017, Representatives Diana DeGette (D-CO) and Tom Reed (R-NY), the Co-Chairs of the Congressional Diabetes Caucus, conducted a bipartisan inquiry into the dramatic insulin price increases.[31] On November 1, 2018, this caucus published a report that provides an overview of the insulin supply

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[27] *See* Letter from U.S. Senator Sanders and U.S. Representative Cummings to U.S. Attorney General Loretta Lynch and FTC Chair Edith Ramirez, at 1 (Nov. 3, 2016), https://www.sanders.senate.gov/wp-content/uploads/sanders-cummings-letter-to-doj-ftc-on-insulin.pdf.

[28] *Id*. (quoting Robert Langreth, *Hot Drugs Show Sharp Price Hikes in Shadow Market*, BLOOMBERG (May 6, 2015)).

[29] *See* Ed Silverman, *Bernie Sanders requests federal investigation of insulin makers for price collusion,* PBS News Hour (Nov. 4, 2016), https://www.pbs.org/newshour/nation/bernie-sanders-requests-federal-investigation-insulin-makers-price-collusion.

[30] *See* Bram Sable-Smith, *How Much Difference Will Eli Lilly's Half-Price Insulin Make?,* Kaiser Health News (Mar. 12, 2019), https://khn.org/news/how-much-difference-will-eli-lillys-half-price-insulin-make/; Carolyn Johnson, *Why treating diabetes keeps getting more expensive,* The Washington Post (Oct. 31, 2016), https://www.washingtonpost.com/news/wonk/wp/2016/10/31/why-insulin-prices-have-kept-rising-for-95-years/.

[31] *See About the Caucus – Goals*, Congressional Caucus on Diabetes, https://diabetescaucus-degette.house.gov.

chain, discusses the drivers behind rising insulin prices, and recommends policy solutions to lower costs.[32] In its report, the Congressional Diabetes Caucus found that the list price of competing insulin formulations appeared to rise in tandem.

77. In February and April of 2019, the Senate Finance Committee wrote Eli Lilly, Novo, and Sanofi, respectively, in order to follow the money trail and better understand how the three largest insulin manufactures and the three largest PBMs price insulin products.[33]

78. At an April 2019 Congressional hearing, Novo's President, Doug Langa, testified on Novo's perpetuation of the insulin pricing overcharges as alleged herein:

> [T]here is this perverse incentive and misaligned incentives [in the insulin pricing system] and this encouragement to keep [reported] prices high. ***And we've been participating in that system because the higher the [reported] price, the higher the rebate.... There's a significant demand for rebates. We spend almost $18***

[32] *See Insulin: A life-saving drug too often out of reach*, https://docs.house.gov/meetings/IF/IF02/20190402/109502/HHRG-116-IF02-20190402-SD001.pdf ("Congressional Diabetes Caucus Report"); *see also Congressional Diabetes Caucus Releases Report on Insulin,* Diabetes Patient Advocacy Coalition, https://www.diabetespac.org/news/congressional-diabetes-caucus-releases-report-on-insulin.

[33] *See*, *e.g.*, *Grassley, Wyden Launch Bipartisan Investigation into Insulin Prices*, GRASSLEY.SENATE.GOV, https://www.grassley.senate.gov/news/news-releases/grassley-wyden-launch-bipartisan-investigation-insulin-prices.

> ***billion.... [I]f we eliminated all the rebates ... we would be in jeopardy of losing [Novo's formulary] positions***.[34]

79. On July 28, 2016, Eli Lilly disclosed that the U.S. Attorney's Office for the Southern District of New York issued a civil investigative demand for information related to contracts with services performed by and payments to PBMs.[35]

80. On May 1, 2017, Eli Lilly announced in a Securities and Exchange Commission filing that it had received civil investigative demands in connection with insulin pricing investigations by the Attorneys General for the States of Washington and New Mexico.[36]

81. The Attorney General for the State of Washington also sent a civil investigative demand to Sanofi regarding insulin pricing and trade practices. [37]

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[34] *Priced Out Of A Lifesaving Drug: Getting Answers on the Rising Cost Of Insulin*, Hearing Before the Subcomm. on House Energy and Commerce, at 44-45, 49 (Apr. 10, 2019), https://www.congress.gov/116/meeting/house/109299/documents/HHRG-116-IF02-Transcript-20190410.pdf (emphasis added).

[35] 2016 Form 10-Q, Eli Lilly and Company, at 45 (July 28, 2016), https://investor.lilly.com/static-files/4ff44c76-ec31-44c4-a032-0691d3e2879f.

[36] *See* 2017 Form 10-Q, Eli Lilly and Company (May 1, 2017), at 43, https://investor.lilly.com/node/35976/html.

[37] *See* 2017 Half-Year Financial Report, Sanofi, at 41, https://www.sanofi.com/dam/jcr:40af4880-d889-43ac-bb.

82. In January 2017, the Attorney General for the State of Minnesota launched civil investigations into Sanofi[38] and Novo[39] regarding the companies' insulin pricing and trade practices.

83. PBM rebate practices continue to be the focus of governmental investigations. *See* FTC Press Release, "FTC Launches Inquiry Into Prescription Drug Middlemen Industry," dated June 7, 2022, at https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

84. On May 23, 2023, the United States House Committee on Oversight and Accountability held a hearing on *The Role of Pharmacy Benefit Managers in Prescription Drug Markets: Self-Interests or Health Care?*. During that hearing, one pharmacist testified:

> The outsized role PBMs take in the pharmacy space has caused many problems for our patients and our practice. The three largest PBMs (Caremark owned by CVS Health which also owns Aetna, Express Scripts owned by Cigna, and Optum owned by UnitedHealthcare) control 80 percent of the market today,1 which means patients are forced by PBMs into using a certain pharmacy, often one owned and operated by the PBM, or they may be forced to get their drugs through the mail even though they want a pharmacist face-to-face in their

[38] *See* 2016 Form 20-F, Sanofi, at 183-84, https://www.sec.gov/Archives/edgar/data/1121404/000119312517069257/d245496d20f.htm.

[39] *See* 2016 Annual Report, Novo Nordisk, at 80, http://www.annualreports.com/HostedData/AnnualReportArchive/n/NYSE_NVO_2016.pdf.

community (See Exhibit A). Patients and their doctors have virtually no say in what drugs are used, since the PBM essentially forces which drugs can be used – not because a drug is better or worse, but because the PBM can make more money from it.

. . .

PBMs contribute to artificially inflating drug costs using expensive name-brand medications when less expensive generic alternatives are available. To do this, PBMs claim that they secure large rebates from the manufacturer to bring the net cost of the product down to below the cost of the generic. Even if this were true (which would require complete transparency and a 100 percent pass-through of all monies that flow from a pharmaceutical manufacturer to a PBM), it does not negate the consumer harm that exists to patients when they are in the deductible phase and are paying more out of pocket for their medication costs. PBMs blame these formulary placements on plan sponsors, but plan sponsors like others in this industry are at the mercy of PBMs and their constant threats of rate hikes.

Another harmful, anticompetitive tactic employed by PBMs is spread pricing, which refers to the difference between how much a PBM reimburses the pharmacy for a drug and the higher price they turn around and charge the plan for the same prescription. For years, community pharmacists have said that PBMs have been playing spread pricing games, contributing to higher drug costs to the detriment of patients and the taxpayer-funded programs the PBMs are supposed to serve. Studies of multiple state Medicaid managed care programs have indicated that PBMs are overcharging taxpayers for their services in Medicaid managed care, reimbursing pharmacies low for medications dispensed, billing the state Medicaid program high for the cost of those medications, and retaining the difference, called "spread."[40]

[40] Written Testimony of Kevin J. Duane, PharmD, U.S. House Committee on Oversight and Accountability, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part I: Self-Interest or Health Care?* (May 23, 2023).

V. Defendants' Kickback Scheme.

85. The PBM Defendants generally pass through only a portion of specified "rebates" they demand from drug manufacturers to health benefit provider clients.[41] Moreover, PBMs have written their contracts to retain for themselves all other payments from drug companies like the Manufacturer Defendants, including, among other things, discounts, "administrative or other fees," and/or side deals, and thus, the PBM Defendants keep substantially more of the moneys received from drug makers than they pass through. The result is that the PBM Defendants profit handsomely from "rebates."[42] And Local 1 and Class members, as described herein, have been injured because the price they paid and continue to pay for the Insulin Drugs was and is artificially inflated as a result of Defendants' illegal schemes, acts, and conspiracy.

[41] *It's Time To Determine How Much Your PBM Is Depriving Your Plan of Rebates: File An "Accounting" Procedure*, Nat'l Prescription Coverage Coalition, http://nationalprescriptioncoveragecoalition.com/its-time-to-determine-how-much-your-pbm-is-depriving-your-plan-of-rebates-file-an-accounting-procedure/ ("*It's Time*").

[42] *How to Dramatically Decrease Your MCO's Rx Coverage Costs*, Managed Care MAG.com (Apr. 2008), https://www.managedcaremag.com/archives/0804/0804.mco_rx.html.

A. The PBM Defendants use a Carefully Designed System of Contractual Language to Hide the True Nature and Amount of Unlawfully Retained Monies.

86. Local 1 and Class members do not know, and could not know, the details of the financial arrangements between the PBM Defendants and the Manufacturer Defendants. These contracts are closely kept trade secrets. Moreover, the PBM Defendants have gone to great lengths to conceal the extent to which the rebates and other payments from the Manufacturer Defendants to the PBM Defendants are actually passed on to the TPP clients of the PBM Defendants.

87. Among other things, substantially all of the contracts between the PBM Defendants and their TPP clients contain notice provisions that require the PBM Defendants give notice to their TPP clients in the event that their contracts might be disclosed. These notice provisions are not necessary or appropriate for the TPPs to conduct business and are inappropriate given that the beneficiaries of both employer-created and publicly created prescription benefit plans have an interest in full disclosure of the contractual provisions that govern administration of their respective plans. The PBM Defendants have consistently relied on the existence of these notice provisions as at least one justification to limit or deny discovery of the rebate terms of these contracts in litigation, even where such disclosure would be governed by strict confidentiality provisions. Indeed, as the United States Senate reported:

> PBMs have been subject to a great deal of scrutiny for their role in rising drug prices. Although they are the centerpiece of drug pricing

> negotiations, their practices and business relationships remain largely opaque. As discussed above, the lack of transparency is due in large part to the confidentiality of contractual relationships PBMs have with both health insurers and drug manufacturers, as well as Federal laws barring disclosure of some information related to these negotiations. While the HHS OIG found that this 'lack of transparency raises concerns that sponsors may not always have enough information to oversee the services and information provided by PBMs,' the industry continues to fight efforts to bring visibility to its operations. Likewise, PBMs were not fully responsive to the Finance Committee's requests during this investigation, variously failing to timely produce documents, produce all of the requested documents, or produce documents that were fully un-redacted.

88. Moreover, even though all the information regarding the computation of the rebates due to the PBM Defendants is generated at the time a prescription is filled and immediately enters their extremely powerful and sophisticated information processing systems, at least some of the PBM Defendants perform all rebate computations and generate invoices to the Manufacturer Defendants by hand. This practice impedes discovery of the total amount paid by the Manufacturer Defendants to the PBM Defendants and thereby hampers any litigation challenging their kickback scheme.

89. In addition to rebates, drug companies like the Manufacturer Defendants routinely pay the PBM Defendants substantial amounts of various "administrative fees" in exchange for, among other things, ensuring a given drug's

formulary placement.[43] As Express Scripts states in its template contract with the City of Flint, Michigan:

> ESI [Express Scripts] provides administrative services to formulary rebate contracted manufacturers, which include, for example, maintenance and operation of the systems and other infrastructure necessary for managing and administering the PBM formulary rebate process and access to drug utilization data, as allowed by law, for purposes of verifying and evaluating the rebate payments and for other purposes related to the manufacturer's products. ESI receives administrative fees from the participating manufacturers for these services. These administrative fees are calculated based on the price of the rebated drug or supplies along with the volume of utilization and do not exceed the greater of (i) 4.58% of the average wholesale price, or (ii) 5.5% of the wholesale acquisition cost of the products. In its capacity as a PBM company, ESI also may receive service fees from manufacturers as compensation for the performance of various services, including, for example, formulary compliance initiatives, clinical services, therapy management services, education services, medical benefit management services, and the sale of non-patient identifiable claim information. These service fees are not part of the formulary rebates or associated administrative fees.[44]

90. An industry expert, Paul Lendner, observed, "If a PBM enters into contracts with drug manufacturers and chooses to give rebates another name — like

[43] Henry C. Eickelberg, *The Prescription Drug Supply Chain "Black Box" — How it Works and Why You Should Care*, Am. Health Pol'y Inst., at 13-14 (2015), https://terrygroup.com/app/uploads/2015/12/December-2015_AHPI-Study_Understanding_the_Pharma_Black_Box.pdf; *see also It's Time*.

[44] Sample PBM Agreement at 28.

administrative fees or health management fees or grants — the PBM will arguably eliminate its obligation to pass through the financial benefits to its clients."[45] Additionally, "a PBM can deprive its clients of rebates by ensuring the rebates are paid on the basis that is not attributable to the clients' drug purchases."[46]

91. PhRMA, an industry group of pharmaceutical manufacturers, has explained:

> In addition to rebates, PBMs often *require* manufacturers to pay administrative service fees for administering, invoicing, and collecting rebate payments. These administrative fees are intended to reimburse the PBM for services provided to the manufacturer and are not generally passed on to the PBM's client.[47]

92. Altarum, a nonprofit research and consulting organization that works with governments and private insurers to improve health outcomes for Medicare and Medicaid beneficiaries, stated:

> The concern is that PBMs, in their role as intermediaries, have diverted much of the potential savings to their own bottom lines, a concern intensified by the lack of transparency around the proprietary rebate amounts. Examples include PBMs retaining more than their agreed

[45] Paul Lendner, *Don't Get Trapped By PBM's Rebate Labeling Games*, Managed Care MAG.com (Jan. 1, 2009), https://www.managedcaremag.com/archives/2009/1/don-t-get-trapped-pbms-rebate-labeling-games.

[46] *Id.*

[47] *Follow the Dollar*, PhRMA (Nov. 2017), at 8, http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf (emphasis added).

> upon share of rebates through re-labeling rebates as fees and PBMs pressuring manufacturers to increase their list prices with a commensurate increase in rebates. This benefits PBMs doubly since they are often paid a percentage of list price and also retain a share of rebates.[48]

93. For example, in a February 14, 2017 letter to HHS regarding PBM practices, Eli Lilly stated that:

> [There] is an emerging practice by some (but certainly not all) of these [PBM] entities to condition a manufacturer's ability to bid for federal government business on the willingness of manufacturer[s] to accept a non-negotiable suite of administrative services at a non-negotiable rate. From Lilly's perspective, this is in effect a "pay-to-play" requirement.[49]

Thus, according to Eli Lilly, PBMs are demanding and drug companies are paying what are labelled administrative fees (which do not flow to the health benefit providers to any significant extent) to PBMs in exchange for formulary placement.

94. As previously alleged, the PBM Defendants represent to Class members, TPP clients, and the public that the "Administrative Fees" or "Manufacturer Administrative Fees" charged by the PBM Defendants to the Manufacturer Defendants as a condition to formulary placement of the Insulin Drugs were, in words or substance, "for administrative services performed by Pharmacy

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[48] Roehrig at 4.

[49] Letter from Josh O'Harra, Assistant General Counsel for Eli Lilly, to Patrice Drew, Office of the Inspector General, Feb. 14, 2017, at 2, https://www.regulations.gov/document?D=HHSIG-2017-0001-0002.

Benefit Manager in relation to the processing, invoicing for or collection of any Rebates" when those services are already performed by the PBM Defendants and paid for by the TPP clients of the PBM Defendants pursuant to the contracts between the TPP clients and the PBM Defendants that represent them.

95. Administrative fees can make up a substantial portion of the total dollar amount of drug company payments to a PBM. According to David Dross, a pharmacy-benefits consultant who has been cited in Senate testimony, administrative fees can amount to 25-30% of total payments from drug companies like the Manufacturer Defendants.[50] Express Scripts revealed in a 2017 lawsuit that it filed against one drug manufacturer that it kept 13 times more in administrative fees than it passed back to its clients through "rebates."[51]

96. That the PBM Defendants have, in fact, retained increasing amounts of rebates and fees for themselves is demonstrated by a March 2019 Pew Center study which analyzed manufacturer rebate levels, health-plan drug expenditures, and PBM

[50] David Dross, *Will Point-of-Sale Rebates Disrupt the PBM Business*?, Mercer (July 31, 2017), https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates-disrupt-the-pbm-business.html.

[51] *Express Scripts Lawsuit Should Raise Everyone's Eyebrows,* Nat'l Prescription Coverage Coalition, http://nationalprescriptioncoveragecoalition.com/express-scripts-lawsuit-should-raise-everyones-eyebrows/. According to Express Scripts' complaint, it entered "rebate agreements" with the drug manufacturer, which required the manufacturer to pay Express Scripts far more in "administrative fees" than the manufacturer paid in "formulary rebates." *Id*.

revenues from drug expenditures during this period.[52] That study found that even though manufacturers paid greater rebates during the period 2012-2016,[53] those rebates did not actually reduce health-plan expenditures on drugs — which increased by 66% from 2012-2016.[54] The report observed that as health benefit providers were being forced to spend more and more on drugs, PBM revenues virtually doubled because they retained increased percentages of rebates for themselves and increasingly took their payments from manufacturers in the form of "fees" that they did not share with their health benefit provider clients.

97. The Pew Center study estimated that:

- in 2012, PBMs retained $11.6 billion in rebates and fees related to drug expenditures (which was composed of $5.7 billion in manufacturer rebates and $5.9 billion in manufacturer fees),

- by 2015 (3 years later), PBMs retained $18.2 billion in rebates and fees related to drug expenditures (which was composed of $7.8 billion in manufacturer rebates and $10.4 billion in manufacturer fees), and

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[52] *See The Prescription Drug Landscape Explored, A look at retail pharmaceutical spending from 2012 to 2016*, March 8, 2019 Pew Center Report, https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored.

[53] Manufacturer rebates increased from $10.2 billion in 2012 to $29.1 billion in 2016. *Id*. at 9.

[54] In 2012, $110.6 billion in commercial health plan premiums went to pay for retail prescription drugs, and by 2016, $183.9 billion of commercial health plan premiums went to pay for retail prescription drugs — a 66% increase in drug expenditures over a four-year period. *Id.* at 8.

- by 2016 (4 years later), PBMs retained $22.4 billion in rebates and fees related to drug expenditures (which was composed of $5.8 billion in manufacturer rebates and $16.6 billion in manufacturer fees).[55]

98. Thus, over a four-year period, due to surging prices based on Defendants' conduct, PBM revenues virtually doubled (from $11.6 billion to $22.4 billion) because PBMs retained more and more manufacturer rebates, and PBM fees (which are not shared with health benefit provider clients) virtually tripled. Notably, PBM-retained monies increased not only in total dollar terms, but also as an increasing percentage of total drug expenditures.

99. While the PBM Defendants pass some percentage of rebates and fees back to the plans, they also retain a large portion of such moneys, in part through misleading labeling of what are essentially kickback payments received from drug companies like the Manufacturer Defendants. This lack of transparency enables the PBM Defendants to label the payments that they negotiate with the Manufacturer Defendants such that they retain control over the amount of kickbacks they keep for themselves. Thus, the hard bargains the PBM Defendants purport to drive for their clients are, in reality, for the benefit of the PBM Defendants themselves.

[55] *Id.* at 13.

B. PBM Defendants Rely on Newly Created GPOs to Further Impede Accurate Accountability of the Nature and Amount of Unlawfully Retained Monies.

100. Adding another layer of opaqueness to the already thick veil of transparency, in recent years the PBM Defendants each formed separate Group Purchasing Organizations ("GPOs") or "Rebate Aggregators." Beginning in 2019, Express Scripts formed Ascent Health Services (based in Switzerland), followed by CVS's formation of Zinc in 2020 and Optum's formation of Emisar Pharma Services (based in Ireland) in 2021. PBMs now use these GPOs to manage rebate negotiations and contracting services with Manufacturers and TPP clients.[56] Notably, "this spate of GPO launches by PBMs came as Congress was debating legislation that would establish new transparency requirements for PBMs."[57]

101. The appearance of GPOs in the already complicated chain of financial transactions between Defendants and PBMs, and TPPs and PBMs creates an additional layer from which PBMs can extract unlawful monies camouflaged as fees. In addition, the foreign incorporation of Optum's and Express Scripts' GPOs creates new hurdles for TPPs seeking formal accountings of the parties' rebates and fees

[56] Federal Trade Commission, *FTP Deepens Inquiry into Prescription Drug Middlemen* (May 17, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-middlemen

[57] Manged Health Care Executive, PBMs are creating GPOs, and Stirring Debate as to Why (July 12, 2022), https://www.managedhealthcareexecutive.com/view/pbms-are-creating-gpos-and-stirring-debate-as-to-why.

collections. To verify any such accountings in person, TPPs would be required to travel to a different country just to confirm all accountings were accurate in order for TPPs to submit proper reports to DHHS or State Agencies in accordance with federal laws.

C. The PBM Defendants Solicit and Receive Kickbacks for Formulary Placement from the Manufacturers that were Not Payment for Services Actually Rendered.

102. In each year during the Class Period, each Defendant received benefits of more than $10,000 under each of the Federal health care programs providing grants, contracts, subsidies, insurance, and other forms of federal assistance, including Medicare, Medicaid, Tricare, CHAMPVA, VA benefits and the Affordable Care Act for the purpose of funding the purchase of the Insulin Drugs prescribed for use by the beneficiaries of such Federal health care programs.

103. The unlawful rebates and fees (*i.e.,* kickbacks) were paid by each of the Manufacturer Defendants to each of the PBM Defendants in connection with each such program.

104. The unlawful rebates and fees (*i.e.,* kickbacks) paid by the Manufacturer Defendants to the PBM Defendants in connection with the purchase of the Insulin Drugs prescribed for use by the beneficiaries of such Federal health care programs exceeded millions of dollars during each year of the Class Period and

such funds were withdrawn, transferred, deposited, and/or exchanged by each Defendant by or through financial institutions.

105. The payment of such rebates and fees by the Manufacturer Defendants to the PBM Defendants as described herein were payments other than for services rendered, *i.e.*, commercial bribes and kickbacks, and constituted a breach of the duty owed by the PBM Defendants to their TPP clients. Thus, in purpose and effect these rebates and payments of fees constituted commercial bribery through unlawful kickbacks.

D. Manufacturers Increased WAC Prices to Maintain Consistent Kickbacks and Bribes to the PBMs, Allowing Both Groups to Profit Illegally.

106. The prices paid by Local 1 and Class members to Defendants for the Insulin Drugs were artificially inflated as part of the illegal schemes, acts, and conspiracy described herein, and the revenue generated by the artificially inflated prices is used by the Manufacturer Defendants to pay the PBM Defendants the kickbacks as so-called "rebates" and "fees."

107. The Manufacturer Defendants improperly inflated the WAC prices of their Insulin Drugs and used the increased monies they received to pay the PBM Defendants the kickbacks.

108. In a well-functioning, competitive market for interchangeable products like the Insulin Drugs, PBMs would exercise the leverage they possess by virtue of

their role in creating and managing formularies to negotiate lower prices from drug companies, including the Manufacturer Defendants.

109. In turn, the Manufacturer Defendants would compete by providing the lowest price in order to obtain a favorable position on the formulary.

110. In other words, a competitive price would provide a legitimate basis to confer formulary status to the least costly medication.

111. However, during the last decade, the PBM Defendants have demanded bribes and kickbacks to eliminate the price-disciplining effects from competition. Because so much of the rebates and fees flow into the PBM Defendants' coffers (rather than being paid to their clients), the PBM Defendants benefit from higher WAC prices because they result in higher percentage rebate and percentage fee payments that they keep for themselves (even though doing so is contrary to the interests of the PBM Defendants' health benefit provider clients).[58]

112. The kickbacks that the PBM Defendants receive for a drug are usually calculated as a percentage of the dollar value of a drug's usage based on its WAC list price — such as 30% of a drug's total unit volume purchases by the PBM's

[58] "The sharp climb in net insulin sales revenues between 2009-2012 reflects data suggesting that insulin list price increases were particularly high during this period." *See* Rosie Collington, *Profits, Innovation and Financialization in the Insulin Industry*, Working Paper No. 120, Abstract–Institute for New Economic Thinking, at 9 (Mar. 30, 2020), https://www.ineteconomics.org/uploads/papers/WP_120-Collington-The-insulin-industry.pdf.

clients multiplied by the WAC list price per unit. The total amount of a drug's sales (and thus the total amount of the rebates and fees paid to a PBM for that drug) are driven by two factors: a drug's list price (WAC or AWP, which is typically WAC plus 20%), and its sales volume. For example, the total purchase amount for 1000 units of a $300 drug is $300,000, and the total purchase amount for 1000 units of a $100 drug is $100,000. If a PBM receives a 30% rebate for both drugs, then the PBM receives $90,000 in rebates for the $300 drug, and $30,000 for the $100 drug.

113. Furthermore, the PBM Defendants benefit from large, annual list price increases by drug companies that occur during the life of a multi-year contract for two reasons. First, increases in a drug's list price increase the dollar amount of the rebate and fee payments that the PBM Defendants get to keep.[59] For example, if a PBM receives a 30% rebate on 1000-unit sales of a $300 drug, and the drug price increases by $100 per unit, then the PBM's rebates increase by $30,000 (from $90,000 to $120,000).

114. In addition, large drug price increases during a multi-year contract can generate additional fees and rebates to PBMs in the form of "price-protection"

[59] "Bloomberg News reported an estimate by an independent market research firm that the list price of Eli Lilly's human insulin analog, Humalog, increased by 138% between 2009 and 2015, while the net price to the manufacturer increased by 6%." *Insulin Access and Affordability Working Group: Conclusions and Recommendations*; Diabetes Care, 41:1299–1311, at 1301-1302 (June 2018), https://doi.org/10.2337/dci18-0019.

benefits that the PBM Defendants do not share with their health benefit provider clients. A recent report on the drug industry noted that, in addition to rebates used to purchase formulary access and market share, price/inflation protection rebates also incentivize drug companies to raise list prices and thereby pay the PBM Defendants for formulary placement:

> At the whole-market level, we sense that the price protection rebate arbitrage game is driving manufacturers to higher list price increases than would otherwise occur.... Price protection rebates between brand manufacturers and PBMs are common, as are fixed rebate agreements between PBMs and a significant portion of their plan sponsors. When brand manufacturers' [list price] increases exceed the price protection threshold, the manufacturers rebate the difference to PBMs, who pocket the difference when these price protection rebates grow faster than the PBMs' fixed rebate commitments to plan sponsors. Thus all else equal in a given category, the product with the more rapid list price increases is more profitable to the PBM. Manufacturers, realizing this, don't want their products disadvantaged, and accordingly are driven to keep their rates of list price inflation at least as high, and ideally just a bit higher, than peers'. Durable list price inflation is the natural result.[60]

[60] Richard Evans, Scott Hinds, Ryan Baum, *US Rx Net Pricing Trends Thru 2Q16*, SSR LLC, 36 (Oct. 5, 2016).

115. As OptumRx's CEO candidly admitted in an October 15, 2016 interview with Modern Healthcare, "the largest players" in the PBM industry — the PBM Defendants — "actually benefit from price increases."[61]

116. This has created a perverse incentive for: (a) the PBM Defendants to give preferential formulary status to higher-priced drugs which come with higher payments to the PBM Defendants, even if doing so is contrary to the health plan clients' interest in favoring lower-priced drugs; and (b) for drug companies such as the Manufacturer Defendants to use high rebate and fee payments to purchase favorable formulary status from the PBM Defendants, instead of trying to ensure favorable formulary status by lowering list prices or limiting list price increases.

117. The PBM Defendants' interest and benefit in favoring high-priced drugs and large price increases (contrary to their clients' interests) makes them ripe targets to be bribed by brand manufacturers such as the Manufacturer Defendants who pay kickbacks (*i.e.*, rebates and fees that flow to the PBM Defendants) to gain the ability to raise list prices without being penalized by the PBM Defendants.

118. A February 2018 white paper issued by the White House Counsel of Economic Advisors states that, through the negotiation of secret rebates, PBMs

[61] *Q&A: We don't set the price. Pharmaceutical manufacturers set the price*, Mod. Healthcare (Oct. 15, 2016), http://www.modernhealthcare.com/article/20161015/MAGAZINE/310159957.

generate enormous profits for themselves while at the same time inducing drug companies to increase their list prices:

> [T]he PBM market is highly concentrated. Three PBMs account for 85 percent of the market, which allows them to exercise undue market power against manufacturers and against the health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves…. Over 20 percent of spending on prescription drugs was taken in as profit by the pharmaceutical distribution system…. ***The size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret. The system encourages manufacturers to set artificially high list prices***.[62]

119. The Manufacturer Defendants' executives have readily admitted that the price increases are directly tied to — and the result of — the bribes and kickbacks to the PBM Defendants. For example, an October 2016 *Wall Street Journal* article reported that Enrique Conterno (president of Eli Lilly's diabetes business) stated that:

> The reason drugmakers sharply raise list prices without a corresponding increase in net price is that PBMs demand higher rebates in exchange for including the drug on their preferred-drug lists.[63]

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[62] *Reforming Biopharmaceutical Pricing at Home and Abroad*, White House Counsel of Econ. Advisors, at 10 (Feb. 2018), https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf (citations omitted) (emphasis added).

[63] Denise Roland and Peter Loftus, "*Insulin Prices Soar While Drugmakers' Share Stays Flat*," The Wall Street Journal (Oct. 7, 2016),

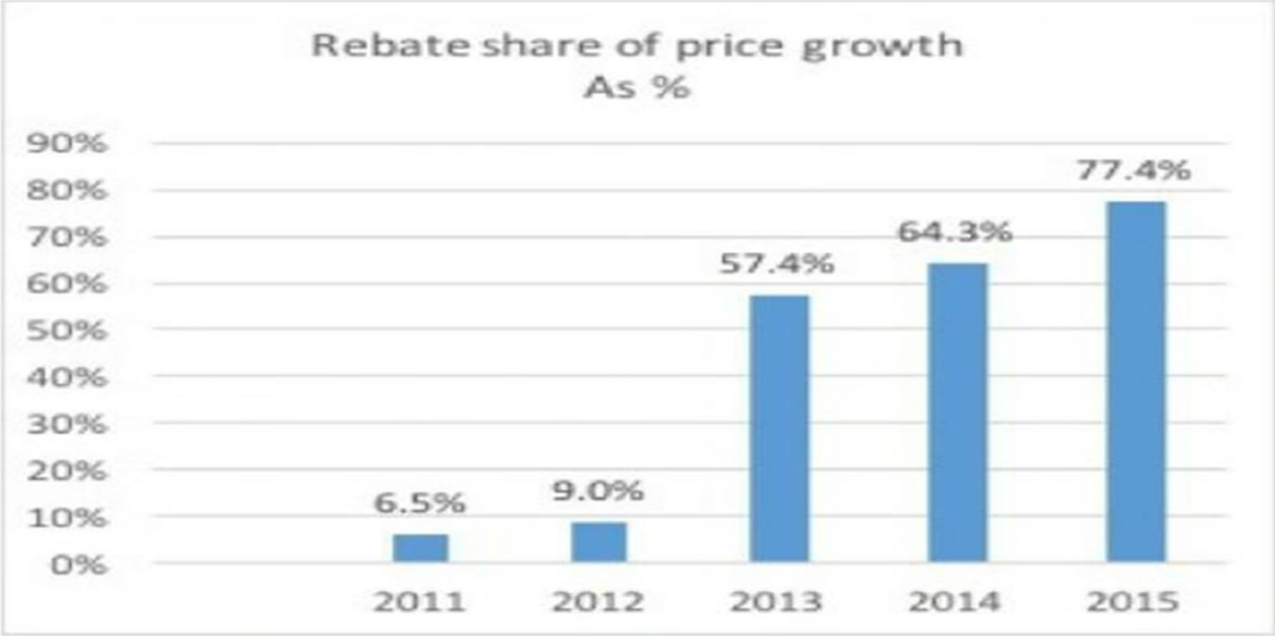
120. Similarly, Novo stated in a 2016 open letter that "as the rebates, discounts and price concessions got steeper, we were losing considerable revenue …. So, we would continue to increase the list [prices] in an attempt to offset the increased rebates, discounts and price concessions to maintain a profitable and sustainable business."[64]

121. As a result of this scheme, drug company payments to PBMs for favorable formulary placement now account for the vast majority of drug list price increases over the last several years. A study conducted by the non-profit, non-partisan Center for Medicine in the Public Interest estimates that, from 2011-2015, rebates paid to PBMs grew as a percentage of total manufacturer list price increases

https://www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat-1475876764.

[64] *Don't Be Duped by Manufacturers' New "Single Digit Price Increase Pledges,"* Nat'l Prescription Coverage Coalition (quoting Jakob Riis, President, Novo Nordisk Inc., *Perspectives from NNI President Jakob Riis on pricing and affordability*" (Nov. 30, 2016)), https://nationalprescriptioncoveragecoalition.com/dont-be-duped-by-manufacturers-new-single-digit-price-increase-pledges/.

from 6.5% to an astounding 77.4%.[65] In 2016, these rebates accounted for 79% of total manufacturer list price increases.[66]



E. Insulin Prices Continue to Soar in Response to Defendants Illegal Kickback Scheme.

122. As the PBM Defendants demanded larger and larger rebates from drug companies, drug prices continued to rise and PBM Defendants' revenues soared.[67]

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[65] Robert Goldberg, Ph.D., *Most of the Increase in Drug Spending Pocketed By PBMs and Insurers: What the Media Missed in Covering the IMS Drug Cost Study*, DrugWonks.com (Apr. 15, 2016), http://drugwonks.com/blog/most-of-the-increase-in-drug-spending-pocketed-by-pbms-and-insurers.

[66] *See* Robert Goldberg, Ph.D., *Reduce Drug Prices by Cutting Out PBM Rebates*, DrugWonks.com (Feb. 8, 2017), https://drugwonks.com/blog/reduce-drug-prices-by-cutting-out-pbm-rebates.

[67] CVS Caremark's Pharmacy Services Segment saw revenues climb from $76 billion in 2013 to more than $120 billion in 2016. Between 2010 and 2016, Express Scripts' revenue jumped from approximately $45 billion to north of $100 billion. As

123. Throughout the Class Period, PBM Defendants profited by retaining a significant percentage of the Manufacturer Defendants' payments to the PBM Defendant (whether characterized as a rebate, fee, or otherwise), retaining the difference between what the PBM Defendant charged the health plan for the Insulin Drug and what the PBM paid the pharmacy for the same drug, and through sales of the Insulin Drugs via their mail-order pharmacies.

124. As a result of the Insulin Pricing Scheme, the WAC prices of Insulin Drugs skyrocketed. Manufacturer Defendants have repeatedly raised the prices of their Insulin Drugs in lockstep manner. By way of example, the WAC price of Sanofi's Lantus SoloStar increased 33.3% from $303 in 2014 to $404 in 2019; the WAC price of Novo's Levemir FlexTouch increased 52% from $303 in 2014 to $462 in 2019; the WAC price of Lilly's Humalog 50-50 Kwikpen increased 64% from $323 in 2013 to $530 in 2017; the WAC price of Sanofi's Apidra Solostar increased

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of December 31, 2017, Express Scripts reported annual drug company payments of $2.58 billion, representing approximately 37% of its total net receivables.

According to Professor Ed Ketz of Penn State, given the significant percentage of total net receivables from drug companies, "we can start thinking of the pharmaceutical companies as customers. They're not just bystanders in this equation." Linette Lopez, "The Feds just asked a huge healthcare company who their real clients are and the answer is totally unsatisfying," Business Insider US (Dec. 7, 2017), http://www.businessinsider.com/sec-looks-into-express-scripts-rebates-from-pharmaceutical-firms-2017-12.

from $302 in 2014 to $521 in 2019; and the WAC price of Novo's Novolog FlexPen increased 70% from $323 in 2013 to $558 in 2018.[68]

125. The negative effects of the Defendants' pricing scheme is still felt in the present. As recent as a Capitol Hill proceeding on May 10, 2023, Senator Bernie Sanders questioned Defendants "Why, in the richest country on Earth, do 1.3 million Americans ration insulin because of the cost? Why are 1 out of 4 Americans not able to afford the prescription drugs their doctors prescribe?" In response, Eli Lily CEO David Ricks acknowledged the bare facts "Higher list prices allow for higher fees and rebates, which can increase patients out of pocket costs. . . ."[69]

VI. Interstate Trade and Commerce

126. As described herein, during the Class Period, Defendants, directly or through one or more of their affiliates, sold the Insulin Drugs throughout the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

127. The business activities of Defendants that are the subject of this action were within the flow of, and substantially affected, interstate trade and commerce.

[68] Staff Report, U.S. Senate Finance Committee, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 6.

[69] Thompson Reuters, *Insulin Makers Testify on Capitol Hill over Prices*, https://www.reuters.com/business/healthcare-pharmaceuticals/pharma-ceos-testify-us-senate-hearing-insulin-prices-2023-05-10/

128. Defendants' and their co-conspirators' conduct, including the marketing and sale of the Insulin Drugs, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States.

129. Defendants' conduct as alleged in this Class Action Complaint has directly and substantially affected interstate commerce as Defendants deprived Local 1 and Class members of the benefits of free and open competition in the purchase of the Insulin Drugs within the United States.

VII. Antitrust and RICO Injury

130. As described herein, during the Class Period, Local 1 and Class members directly purchased the Insulin Drugs from the Defendants. As a result of Defendants' unlawful kickback scheme, Local 1 and Class members paid more for the Insulin Drugs than they would have and thus suffered substantial damages. This is a cognizable injury and constitutes compensable harm under the federal antitrust laws and the RICO statute.

131. As a result of Defendants' unlawful conduct, Local 1 and Class members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid for the Insulin Drugs. The full amount of such damages will be calculated after discovery and upon proof at trial.

VIII. Fraud, Fraudulent Concealment and Equitable Tolling

132. During the Class Period, Defendants affirmatively and fraudulently concealed their unlawful conduct against Local 1 and Class members.

133. Because of Defendants' active concealment, Local 1 and Class members had no knowledge of Defendants' unlawful conduct as alleged herein or of facts sufficient to place them on inquiry notice of the claims set forth herein, until at least November of 2016, when news sources began publishing information about the Senate investigation.

134. Given the government's role as the single largest healthcare payor in the United States, the government's inability to uncover any evidence of Defendants' unlawful scheme to artificially raise and fix prices until late 2016 demonstrates that Local 1 and Class members could not have discovered Defendants' illegal conduct prior to that time.

135. To facilitate their illegal commercial bribery/kickback scheme, Defendants carefully concealed evidence of their unlawful conduct and their pricing structures and sales figures for the Insulin Drugs.

136. Defendants went to great lengths to conceal their program of kickbacks to increase prices to direct purchasers, even concealing it from investors. For instance, Novo concealed its relationship with PBMs, preventing investors from obtaining accurate information regarding Novo's insulin sales. In Novo's 2015

Annual Report, the company stated its "[p]roduct success is largely based on competition on efficacy, safety, quality and price." Novo (and all of the other Defendants) knew that the selection of the Insulin Drugs for formulary placement was driven by the kickbacks, not efficacy, safety, quality or price.

137. Information regarding the government investigation of Defendants' alleged unlawful conduct in the analog insulin market was not made public until November 2016.

138. Defendants made misleading public statements regarding rebates, price increases, and their actual profits from the sale of insulin drugs.

139. For example, in Novo's 2009 and 2011 Annual Reports it stated:

> Customer rebates are offered to a number of managed healthcare plans. These rebate programmes imply that the customer receives a rebate after attaining certain performance parameters relating to product purchases, formulary status and pre-established market share milestones relative to competitors.[70]

140. In Novo's 2013 Annual Report it stated:

> The principal market risks Novo Nordisk experiences are:
>
> - price pressure and reimbursement restrictions by payers
> - the launch of new products by established competitors

[70] 2009 Annual Report, Novo Nordisk, at 56, https://www.annualreports.com/HostedData/AnnualReportArchive/n/NYSE_NVO_2009.pdf; 2011 Annual Report, Novo Nordisk, at 60, https://www.annualreports.com/HostedData/AnnualReportArchive/n/NYSE_NVO_2011.pdf.

- increased competition from producers of biosimilar medicines in key markets. Europe, China and the US are all main markets for Novo Nordisk where payers – both governments and private payers – take measures to limit spending on medicines, typically by driving down prices, demanding higher rebates and/or restricting access to and reimbursement of products.[71]

141. In Novo's 2014 Annual Report, Novo stated:

> These sales drivers are expected to be partly countered by an impact from increased rebate levels in the US, intensifying competition within diabetes and biopharmaceuticals as well as macroeconomic conditions in a number of markets in International Operations.[72]
>
> IMPACT OF US REBATES
>
> A significant factor in net operating assets also relates to movement in the provision for sales rebates in the US, presented as Short-term provisions in the balance sheet. The movement in 2014 reflects growth in US sales, and changes in product and rebate programme mix, countered by the effect of faster collection from pharma benefit managers and authorities. The increase in inventory level partly reflects additional safety stock. Trade receivables and fixed assets have developed in line with Operating profit.[73]

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[71] *See* 2013 Annual Report, Novo Nordisk, at 42, https://www.annualreports.com/HostedData/AnnualReportArchive/n/NYSE_NVO_2013.pdf.

[72] *See* 2014 Annual Report, Novo Nordisk, at 8, https://www.annualreports.com/HostedData/AnnualReportArchive/n/NYSE_NVO_2014.pdf.

[73] *Id*. at 71.

142. On November 30, 2016, Novo issued a press release regarding AWP prices and actual profits that, among other things, stated:

> News reports on drug prices have left the public with an impression that companies like ours realize all the profits from the "list price" increases we've made over the last decade. In other words, a list price increase by XX percent leads to an automatic XX percent profit for the drug maker. We believe that is misleading and here's why: As the manufacturer, we do set the "list price" and have full accountability for those increases. However, after we set the list price, we negotiate with the companies that actually pay for the medicines, which we call payers. This is necessary in order for our medicines to stay on their preferred drug list or formulary. The price or profit we receive after rebates, fees and other price concessions we provide to the payer is the "net price." The net price more closely reflects our actual profits.[74]

143. In 2009, Sanofi stated in its 20-F Form:

> In addition to the pricing pressures they exert, governmental and private third-party payers and purchasers of pharmaceutical products may reduce volumes of sales by restricting access to formularies or otherwise discouraging physician prescriptions of our products. In the United States, the Democrats, who currently hold the majority in Congress and the presidency, have introduced a reform proposal designed to increase the government's role in determining the price, reimbursement and the coverage levels for healthcare-related expenses.[75]

144. In 2013 and 2014, Sanofi stated in its 20-F Form:

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[74] *See* Press Release.

[75] *See* 2009 20-F Form, Sanofi, at 8, https://www.sanofi.com/dam/jcr:e2bd57d6-c63d-47d1-bcad-ff3bc77629e2/20F_2009-A.pdf.

> ***The pricing and reimbursement of our products is increasingly affected by government and other third parties decisions and cost reduction initiatives.***
>
> The commercial success of our existing products and our product candidates depends in part on the conditions under which our products are reimbursed. Our products continue to be subject to increasing price and reimbursement pressure due to, amongst others:
>
> - price controls imposed by governments in many countries;
> - removal of a number of drugs from government reimbursement schemes (for instance products determined to be less cost-effective than alternatives);
> - increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates;
> - increase in cost containment policies related to health expenses in a context of economic slowdown; and
> - the tendency of governments and private health care providers to favor generic pharmaceuticals.
>
> In addition to the pricing pressures they exert, governmental and private third-party payers and purchasers of pharmaceutical products may reduce volumes of sales by restricting access to formularies or otherwise discouraging physician prescriptions of our products. For example, in the United States, the federal health care reform law is increasing the government's role with respect to price, reimbursement and the coverage levels for healthcare services and products within the large government healthcare sector.[76]

145. In 2011, Eli Lilly stated in its Annual Report:

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[76] *See*, 2013 20-F Form, Sanofi, at 10, https://www.sanofi.com/dam/jcr:c5b48593-99ce-4d6b-83c0-ab32eafd7a45/20F_SANOFI_2013.pdf; 2014 20-F Form, Sanofi, at 11, https://www.sanofi.com/dam/jcr:5cb50393-cb23-443f-b989-98d8d8be36f6/Sanofi_20-F_2014.pdf.

> We maintain special business groups to service wholesalers, pharmacy benefit managers, managed-care organizations, government and long-term care institutions, hospitals, and certain retail pharmacies. In response to competitive pressures, we have entered into arrangements with some of these organizations providing for discounts or rebates on Lilly products.[77]

146. In 2013, Eli Lilly stated in its Annual Report:

> MCOs typically maintain formularies specifying which drugs are covered under their plans. Exclusion of a drug from a formulary can lead to its sharply reduced usage in the MCO patient population. Consequently, pharmaceutical companies compete aggressively to have their products included. Where possible, companies compete for inclusion based upon unique features of their products, such as greater efficacy, fewer side effects, or greater patient ease of use. A lower overall cost of therapy is also an important factor. Products that demonstrate fewer therapeutic advantages must compete for inclusion based primarily on price. We have been generally, although not always, successful in having our major products included on MCO formularies.[78]

147. In 2017, Eli Lilly spokesperson Julie Williams stated:

> The amount the manufacturer receives after all discounts and rebates are applied is considerably less than the list price. For example, the net price for Humalog – our most commonly used insulin – increased by 4 percent over the

[77] *See*, 2011 Annual Report, Eli Lilly, at 3, https://investor.lilly.com/static-files/96daf2d4-f329-42be-9069-fd158c2857ad.

[78] *See*, 2013 Annual Report, Eli Lilly, at 6, https://investor.lilly.com/static-files/8fc35b0c-76ef-4669-bb22-83cebd322f5e.

> five-year period of 2009 to 2014, which is a much smaller increase than what some consumers have experienced.[79]

148. Defendants made the above public statements to conceal their unlawful scheme to demand and receive kickbacks and thereby artificially inflate the price of the Insulin Drugs.

149. These statements were false and misleading because, *inter alia*, they failed to disclose to Local 1 and Class members that the increased prices that distributors were forced to pay for the Insulin Drugs were not a function of the need to preserve Defendants' actual profits or other appropriate market forces. These misleading statements concealed the kickback scheme.

150. In these public statements, Novo told investors and the public that it faced pressures to reduce prices, with potential reduction in revenues, blaming government and private payers seeking to limit spending. Eli Lilly led investors and the public to believe competition for formulary listing depended on competition, efficacy, and other attributes, and not the amount of kickbacks paid. Sanofi led investors and the public to believe the pricing of its products was because of pressures on prices from government and third parties and generic competition, concealing the role kickbacks played in price increases.

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[79] *See The High Cost of Insulin (Plus a Plea to Lilly, Novo, and Sanofi)*, HEALTHLINE.COM (Feb. 22, 2106), http://www.healthline.com/diabetesmine/high-cost-insulin-and-plea-to-lilly#4.

151. PBMs are so secretive about their collection and distribution of drug company payments that, during a client audit, the PBM Defendants (i) require preapproval of the client's chosen auditor; (ii) restrict the number of drug company contracts that can be reviewed to a very limited number; (iii) restrict the number of claims and time period that can be reviewed; (iv) refuse to allow any drug company contract to be copied; (v) require a PBM representative to sit with every auditor that is reviewing a drug company contract; and (vi) refuse to allow any auditor to copy by hand the terms of any drug company contract, among other restrictions.

152. Moreover, even though all the information regarding the computation of the rebates due to the PBM Defendants is generated at the time a prescription is filled and immediately enters their extremely powerful and sophisticated information processing systems, at least some of the PBM Defendants perform all rebate computations and generate invoices to the Manufacturer Defendants by hand, which impedes discovery of the total amount paid by the Manufacturer Defendants to the PBM Defendants and thereby hampers any litigation challenging their kickback scheme.

153. Given all of the above, Local 1 and Class members could not have discovered the violations alleged herein earlier than late 2016, because Defendants acted in secret, concealed the nature of their unlawful conduct and acts in furtherance thereof, and fraudulently concealed their activities through various other means and

methods designed to avoid detection. The conspiracy was by its nature self-concealing.

154. Additionally, the statute of limitations was tolled by the filing of *Insulin Direct Purchaser Litigation*, Case No. 20-cv-03426 (D.N.J.).

155. As a result of Defendants' fraudulent concealment of their illegal conduct, any applicable statute of limitations affecting the rights of action of Plaintiffs and Class members have been tolled.

IX. Class Action Allegations

156. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(2), and (b)(3), Local 1 brings this action on behalf of the following direct purchaser class:

> All entities that directly purchased NovoLog, Humalog, Levemir, and/or Lantus from one or more Defendants in the United States or its territories at any time from January 1, 2009 until [the date of the class certification order].
>
> Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates; all governmental entities; individual purchasers or end consumers; and any judicial officer presiding over this litigation, members of their immediate family, and their judicial staff.

157. Local 1 believes there are dozens of Class members that are geographically dispersed throughout the United States. As a result, joinder of all members of the Class is impracticable.

158. Class members are readily identifiable from information and records maintained by Defendants.

159. Plaintiffs' claims are typical of the claims of Class members. Plaintiffs' interests are not antagonistic to the claims of other Class members, and Plaintiffs possess no material conflicts with any other Class members that would make class certification inappropriate.

160. Plaintiffs and all Class members were damaged by the same wrongful conduct of Defendants. Plaintiffs and all Class members directly purchased one or more of the Insulin Drugs from Defendants, and therefore possess the requisite standing.

161. Plaintiffs will fairly and adequately protect and represent the interests of all Class members. Plaintiffs' interests are consistent with, and not antagonistic to, those of Class members.

162. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular expertise pursuing class action litigation involving alleged antitrust and RICO violations.

163. Questions of law and fact common to Plaintiffs and Class members predominate over questions that may affect only individual Class members because

Defendants have acted on grounds generally applicable to the entire Class. As a result, determining damages with respect to the Class as a whole is appropriate.

164. The predominant common legal and factual questions applicable to all Class members include, but are not limited to, the following:

a. Whether Defendants engaged in a kickback scheme and thereby committed commercial bribery;

b. Whether such conduct is a violation of Section 2(c) of the Robinson-Patman Act;

c. The effect of such unlawful bribery on the prices of the Insulin Drugs in the United States during the Class Period;

d. Whether Defendants engaged in mail and wire fraud in carrying out their unlawful kickback/price fixing scheme;

e. Whether Defendants engaged in commercial bribery chargeable as such and punishable under state law;

f. Whether Defendants engaged in commercial bribery in violation of 18 U.S.C. §1341;

g. Whether the Manufacturer Defendants paid kickbacks to the PBM Defendants that provide ERISA benefit plan services to employer sponsored health benefit plans with the intention of influencing the choice of analog insulin to include in the benefit plan formularies that

determine whether and to what extent a particular insulin is available to patients on favorable terms in violation of 18 U.S.C. § 1954;

h. Whether Defendants engaged in commercial bribery in violation of the Travel Act, 18 U.S.C. § 1952, for the reasons alleged in paragraph 4(e) of this Class Action Complaint;

i. Whether Defendants were engaged in one or more "enterprises" within the meaning of the federal RICO statute;

j. Whether Defendants operated such RICO enterprise(s) through a pattern of racketeering activity including mail fraud, wire fraud, and commercial bribery in violation of state law and 18 U.S.C. §§ 1341, 1343, 1952, and 1954.

k. Whether the alleged illegal conduct engaged in by Defendants comprised racketeering activity, in violation of federal RICO laws; and

l. Whether, and to what extent, Defendants' RICO violations caused injury to Plaintiffs and Class members in their business, trade, or property.

165. Those common questions do not vary among Class members. As a result, the Court and the jury may resolve those issues without reference to the individual circumstances of any member of the Class.

166. Class action treatment is a superior method for the fair and efficient adjudication of the claims asserted by all Class members. Such treatment will permit many similarly situated entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender.

167. The benefits of proceeding through the class mechanism, including providing all Class members a method for obtaining redress on claims that they could not practicably pursue individually, substantially outweigh potential difficulties in the management of this litigation as a class action.

168. Plaintiffs know of no special difficulty to be encountered in the management of this action that would preclude its maintenance as a class action.

X. Claims for Relief

COUNT ONE
VIOLATION OF THE ROBINSON-PATMAN ACT, 15 U.S.C. § 13(c) (AGAINST ALL DEFENDANTS EXCEPT OPTUMRX)

169. Plaintiffs hereby incorporate by reference the allegations contained in the preceding paragraphs 1 - 168 of this Class Action Complaint.

170. Section 2(c) of the Robinson-Patman Act provides:

> It shall be unlawful for any person engaged in commerce, in the course of such commerce, to pay or grant, or to receive or accept, anything of value as a commission, brokerage, or other compensation, or any allowance or discount in lieu thereof, except for services rendered in connection with the sale or purchase of goods, wares, or merchandise, either to the other party to such transaction or to an agent,

> representative, or other intermediary therein where such intermediary is acting in fact for or in behalf, of is subject to the direct or indirect control, of any party to such transaction other than the person by whom such compensation is so granted or paid.

15 U.S.C. § 13(c).

171. By engaging in the kickback and commercial bribery scheme described herein, Defendants have engaged in commercial bribery in violation of Section 2(c) of the Robinson-Patman Act, 15 U.S.C. § 13(c).

172. The Manufacturer Defendants artificially increased the price for the Insulin Drugs based on the commercial bribery and kickback scheme described herein.

173. The PBM Defendants sought, and the Manufacturer Defendants paid, kickbacks, bribes, and other unearned sums.

174. Pursuant to the kickback and commercial bribery scheme described above, Defendants created illegal inducements that resulted in artificially inflated prices.

175. As a result of Defendants' unlawful conduct, Local 1 and Class members purchased Insulin Drugs at artificially inflated prices.

176. There is no appropriate or legitimate business justification for Defendants' anticompetitive conduct.

177. Defendants' unlawful conduct has resulted in competitive injury to Local 1 and Class members by unduly restraining, hindering, suppressing, and/or eliminating competition in the sale of commodities in interstate commerce.

178. As a direct and proximate result of Defendants' unlawful actions detailed herein, Local 1 suffered substantial economic losses in the form of overcharges for the Insulin Drugs.

179. Local 1 and Class members are entitled to recover treble damages and costs of suit, including reasonable attorneys' fees, pursuant to Section 4(a) of the Clayton Act, 15 U.S.C. § 15(a).

COUNT TWO
VIOLATION OF RICO, 18 U.S.C. § 1962(c) (AGAINST ALL DEFENDANTS EXCEPT OPTUMRX)

180. Plaintiffs hereby incorporate by reference the allegations contained in the paragraphs 1 - 179 of this Class Action Complaint.

181. For purposes of this claim, the RICO "enterprises" are associations-in-fact consisting of (a) one of the three PBM Defendants that administers insurance coverage of the Insulin Drugs, including its directors, employees, and agents, and (b) one of the Manufacturer Defendants, including its directors, employees, and agents. These association-in-fact enterprises are collectively referred to herein as the "Insulin Pricing Enterprises."

182. The Insulin Pricing Enterprises are as follows.

- **The CVS Caremark-Manufacturer Insulin Pricing Enterprises.** The CVS-Manufacturer Enterprises are three separate associations-in-fact, each consisting of CVS Caremark (including its directors, employees, and agents)which administers purchases of insulins , and a Manufacturer Defendant(including its directors, employees, and agents): (1) the CVS Caremark-Eli Lily association-in-fact enterprise; (2) the CVS Caremark-Novo association-in-fact enterprise and (3) the CVS Caremark-Sanofi association-in- fact enterprise

- **The Express Scripts-Manufacturer Enterprises.** The Express Scripts-Manufacturer Enterprises are three separate associations-in-fact, each consisting of Express Scripts (including its directors, employees, and agents) which administers purchases of insulins , and a Manufacturer Defendant (including its directors, employees, and agents): (1) Express Scripts-Eli Lily association-in-fact enterprise; (2) the Express Scripts-Novo association-in-fact enterprise; and (3) the Express Scripts-Sanofi association-in- fact enterprise.

- **The Optum-Manufacturer Insulin Pricing Enterprises.** The Optum-Manufacturer Enterprises are three separate associations-in-fact, each consisting of Optum (including its directors, employees, and agents), which administers purchases of insulins insulins and a Manufacturer Defendant (including its directors, employees, and agents): (1) the Optum-Eli Lily association-in-fact enterprise; (2) the Optum-Novo association-in-fact enterprise; and (3) the Optum-Sanofi association-in- fact enterprise.[80]

183. Each Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanging bribes and kickbacks — falsely and misleadingly labeled as "rebates" or "fees" — for preferred formulary positions for

[80] Having directly purchased insulins through Caremark CVS and Express Scripts only, Local 1 does not assert a U.S.C. § 1962(c) claim against Optum.

the Manufacturer Defendants' particular Insulin Drug as treatments for type 1 and 2 diabetes.

184. Each Enterprise has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between the particular Manufacturer Defendant and PBM Defendant.

185. As to each Enterprise, (i) there is a common communication network by which the particular Manufacturer Defendant and PBM Defendant respectively share information on a regular basis, and (ii) the particular Manufacturer Defendant and PBM Defendant function as continuing but separate units. At all relevant times, each Enterprise was operated and conducted by the particular Manufacturer Defendant and PBM Defendant for criminal and fraudulent purposes, namely, carrying out the bribery and kickback scheme.

186. Each Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common and/or shared purposes of selling, promoting, and recommending for purchase, and administering prescriptions for the Insulin Drugs and deriving secret profits from these activities.

187. These profits are greater than Defendants could obtain absent their fraudulent concealment of the true nature of substantial "rebates" and other fees from the Manufacturer Defendants to the PBM Defendants.

188. As part of and to accomplish the common purpose of the Insulin Pricing Enterprises, the Manufacturer Defendants systematically paid bribes and kickbacks — falsely labeled as rebates, administrative fees, and/or other monies — to the PBM Defendants in exchange for exclusive and/or favorable placement of their Insulin Drugs on the formularies maintained by the PBM Defendants on behalf of their respective TPP clients. The Manufacturer Defendants did so willfully, knowing that the sales of the Insulin Drugs were based on inflated list prices.

189. The CVS Caremark and Express Scripts Insulin Pricing Enterprises then reported the Manufacturer Defendants' list price increases to health benefit providers, such as Local 1, while simultaneously concealing that the true reason for the price increases was to fund bribes and kickbacks to the PBM Defendants in exchange for formulary placement, and also to increase the dollar value of those bribes and kickbacks, and to increase profits to both the Manufacturer Defendants and to the PBM Defendants.

190. As outlined herein, the commercial bribes and kickbacks paid by the Manufacturer Defendants to the PBM Defendants, which the PBM Defendants solicited and accepted, violated federal and state laws prohibiting commercial bribery as follows:

a. The bribes and kickbacks constitute commercial bribery chargeable as such and punishable by imprisonment under state law.

b. Given that the PBM Defendants provide ERISA benefit plan services to employer sponsored ERISA benefit plans (i.e., each an "employee welfare benefit plan" under 29 U.S.C § 1002(1)) that furnish health coverage for over 180 million American residents, the Insulin "rebates" and "fees" at issue here were solicited and received by the PBM Defendants and paid by the Manufacturer Defendants with the intention of influencing the choice of analog insulin to include in the benefit plan formularies that determine whether and to what extent a particular insulin is available to patients on favorable terms, in direct violation of 18 U.S.C § 1954;

c. The solicitation, payment and receipt of Insulin kickbacks constitute violations of the Travel Act, 18 U.S.C. § 1952, which:

   i. makes it a crime to engage in "bribery … in violation of the laws … of the United States," with 18 U.S.C.§ 666(a), (b) outlawing bribery by making it a felony for an agent[81] of an organization or government "to corruptly solicit[ ] or demand[ ] for the benefit of any person, or accept[ ] or agree[ ] to accept anything of value from any person, intending to be influenced or rewarded in connection with any business, transaction, or series of transactions of such organization … involving anything of value of $5,000 or more" where the "organization … receives, in any one year period, benefits in excess of $10,000 under a Federal program involving a grant, contract, subsidy, loan guarantee, insurance, or other form of Federal assistance;

[81] For this purpose, "the term 'agent' means a person authorized to act on behalf of another person or a government." *See* 18 U.S.C. § 666(d)(1) (*see* 18 U.S.C. §1961(1)(B)).

ii. prohibits carrying on of interstate activities in violation of 18 U.S.C. § 1957 (*see* 18 U.S.C. §1961(1)(B)). Section 1957 provides that it is a federal crime to "knowingly engage[ ] … in a monetary transaction in criminally derived property of a value greater than $10,000 and is derived from specified unlawful activity." For this purpose:

- The term "monetary transaction" means a "deposit, withdrawal, transfer, or exchange, in or affecting interstate … commerce, of funds or a monetary instrument … by, through, or to a financial institution." 18 U.S.C. § 1957(f)(1).

- "Proceeds" means "any property derived from or obtained or retained, directly or indirectly, through some form of unlawful activity." 18 U.S.C. § 1957(f)(3) (citing 18 U.S.C. § 1956(c)(9)).

- The term "specified unlawful activity" includes "any activity constituting an offense involving a Federal health care offense." 18 U.S.C. § 1957(f)(3) (citing 18 U.S.C. § 1956(c)(7)(F)).

- A "'Federal health care offense' means a violation of … section 1128B of the Social Security Act (42 U.S.C. 1320a-7b)." 18 U.S.C. §24(a)(1).

- Subsection (b) of 42 U.S.C. §1320a-7b prohibits any person from knowingly and willfully soliciting or receiving "any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind" in exchange for "recommending purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal health care program."

- For this purpose, a "Federal health care program" is defined as "any plan or program that provides health

> benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government" or certain state health care plans funded or approved by the federal government; specifically, Medicaid under subtitle XIX of title 42, block grants for maternal and child care under subtitle V of title 42, and block grants for social services under subtitle XX.A of title 42. *See* 42 U.S.C. §1320a-7b(f) (citing 42 U.S.C. 1320a-7(h)).

d. The solicitation, payment, and receipt of Insulin kickbacks constitute violations of 18 U.S.C. §1957, which prohibits knowingly engaging in monetary transactions in property having a value greater than $10,000 derived from violations of the AKS taking place in the United States or its territories and affecting interstate commerce.

191. The Manufacturer Defendants' list price increases, disseminated through the U.S. mail and interstate wires, were fraudulent, in that they were artificially inflated to fund the bribes and kickbacks, which the Insulin Pricing Enterprises concealed.

192. The Insulin Pricing Enterprises also fraudulently concealed the economic purpose of these list price increases for the Manufacturer Defendants and the PBM Defendants: the increases ultimately result in higher profits for the Manufacturer Defendants, enabling them to purchase formulary access without requiring significant price reductions; and they result in higher profits for the PBM Defendants, which are paid rebates, fees, and other payments based on the

Manufacturer Defendants' list price increases and sales volume. In addition, the Manufacturer Defendants, as described above, realized significant increases in net profit through their substantial list prices increases, notwithstanding the increased payments (bribes and kickbacks) to the PBM Defendants necessary to secure and maintain formulary placement of the Insulin Drugs and resulting insulin sales.

193. The Insulin Pricing Enterprises also falsely and fraudulently represented to the TPP clients of the PBM Defendants, to Class members, and to the public through the U.S. mail and interstate wires that the "Administrative Fees" or "Manufacturer Administrative Fees" charged by the PBM Defendants to the Manufacturer Defendants as a condition to formulary placement of the Insulin Drugs were, in words or substance, "for administrative services performed by Pharmacy Benefit Manager in relation to the processing, invoicing for or collection of any Rebates" when those services are already performed by the PBM Defendants and paid for by the TPP clients of the PBM Defendants pursuant to the contract between the TPP clients and the PBM Defendants that represent them.

194. Each Insulin Pricing Enterprise also shares a common purpose of perpetuating the use of inflated Insulin Drug list prices. The Manufacturer Defendants required the inflated Insulin Drug list prices in part to fund the bribes and kickbacks to the PBM Defendants in exchange for favorable formulary positions. The PBM Defendants share this common purpose because the inflated Insulin Drug

list prices increase the value of the rebates, fees, and other monies they can keep, and thus increase their profits.

195. Formulary placement determines which drugs are covered and prescribed for purchase. Given that rebates and other fees to the PBM Defendants are determined and paid based in part on sales, the PBM Defendants provided formulary placement to the Insulin Drugs to ensure prescriptions and sales of those insulin products, maximizing their financial gains. As a result, the PBM Defendants have, in concert with the Manufacturer Defendants and through the respective Insulin Pricing Enterprises, engaged in hidden profit-making schemes, the PBM Defendants garnering rebates and other fees from the Manufacturer Defendants that the PBM Defendants, to a significant extent, keep, and do not share with or provide to their health benefit provider clients. The Manufacturer Defendants, meanwhile, unlawfully and fraudulently obtained sales, market share, and profits from the Insulin Drugs.

196. Each of the Insulin Pricing Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between each Manufacturer Defendant and each PBM Defendant that is an associate in the respective enterprise. As to each of the Insulin Pricing Enterprises, there is a common communication network by which each Manufacturer Defendant and each PBM Defendant shares information on a regular basis, including

information regarding insulin prices. As to each of the Insulin Pricing Enterprises, each Manufacturer Defendant and each PBM Defendant functioned as a continuing unit. At all relevant times, each of the Insulin Pricing Enterprises was operated for criminal and fraudulent purposes, namely, carrying out the bribery and kickback scheme and its concealment.

197. At all relevant times, the Insulin Pricing Enterprises had an existence separate and distinct from that of its members. Eli Lilly, Novo, Sanofi, CVS Caremark, Express Scripts and Optum are distinct corporate entities. Further, each member of the respective RICO Enterprises has an existence separate and apart from the pattern of racketeering activities of the RICO Enterprise. Each Defendant carries on distinct businesses and operations. However, as alleged and described herein, each member of each Insulin Pricing Enterprise was essential to the operation of the scheme conducted through Insulin Pricing Enterprises.

198. The PBM Defendants, at all relevant times, have been knowing and willing participants in the conduct of the respective Insulin Pricing Enterprises, and have reaped large profits from that conduct. The PBM Defendants used their position to receive bribes and kickbacks for the Insulin Drugs from the Manufacturer Defendants and profit from the Manufacturer Defendants' inflated list prices. The PBM Defendants have represented to their respective health benefit provider clients and the public that the rebates lower drug costs when, in fact, as the PBM Defendants

are well aware, the inflated list prices required to fund the bribes and kickbacks to them in exchange for favorable formulary placement increased drug costs, including list prices and downstream reimbursement and cost-sharing obligations of health benefit providers and their members. In addition, as part of and to further the respective schemes, the PBM Defendants misrepresent and/or conceal from Local 1 and Class members, from health benefit provider clients, plan members, and the public the existence, amount, and purpose of the rebates, fees, and/or other monies the PBM Defendants are paid by the Manufacturer Defendants as well as the effect of the rebates, fees, and/or other monies on the Insulin Drugs' list prices, and also publish, distribute, and disseminate materials and information concerning the Insulin Drugs' list prices, net prices, and the purpose of "rebates" and so-called "discounts" to conceal the Insulin Pricing Enterprises' schemes.

199. But for the Insulin Pricing Enterprises' common purpose of inflating the Manufacturer Defendants' list prices to fund the bribes and kickbacks, the list prices would not have been artificially inflated, or would not have been artificially inflated to the same extent, and the PBM Defendants would have had the incentive to disclose the fraudulent and collusive inflation of the Manufacturer Defendants' list prices, and would have used their control over the management and administration of their clients' formularies to penalize the Manufacturer Defendants'

undue price increases. By concealing this information, the PBM Defendants and the Manufacturer Defendants perpetuated the conduct of the Insulin Pricing Enterprises.

200. The PBM Defendants readily participated in the scheme so that they could continue to accept kickbacks from the Manufacturer Defendants that were calculated based on the Insulin Drugs' list price.

201. In order to effectuate the scheme, each Manufacturer Defendant and each PBM Defendant met on a regular basis to discuss insulin prices, formulary position, rebates, administrative fees, other monies to the PBM Defendant, and coordination of all of the above.

202. Further, the common communication network between each PBM Defendant and each Manufacturer Defendant effectuated the purpose of implementing the list price inflation-rebate-commercial bribery scheme and the exchange of financial rewards for the PBM activities that benefitted — and continue to benefit — the Manufacturer Defendants, as well as the PBM Defendants.

203. At all relevant times, each Manufacturer Defendant and each PBM Defendant knowingly, purposefully, and willingly engaged and participated in the list price inflation-rebate-commercial bribery scheme and the predicate acts of racketeering activity through each Insulin Pricing Enterprise, and reaped substantial profits from that scheme.

204. The CVS Caremark-Manufacturer and Express Scripts-Manufacturer Enterprises (CVS Caremark-Eli Lily, CVS Caremark-Novo, CVS Caremark-Sanofi, Express Scripts-Eli Lily, Express Scripts-Novo, and Express Scripts-Sanofi) knowingly made material misrepresentations and/or omissions to Local 1 and Class members as well as to the PBM Defendants' health benefit provider clients, plan members, and to the general public in furtherance of the price inflation and rebate scheme. The material misrepresentations and omissions included:

a. The reasons for the list price increases of the Insulin Drugs

b. Whether the PBM Defendants' "kickbacks" for formulary placement were for payment for services actually rendered;

c. The existence, purpose, and amount of the bribes and kickbacks and other monies paid to the PBM Defendants;

d. The effect of the rebates, fees, and other monies on Direct Purchaser Prices;

e. The effect of the rebates, fees, and other monies on the PBM Defendants' development, management, and administration of formularies;

f. The extent to which Defendants negotiated rebates, fees, and other monies for the Insulin Drugs in good faith and for a proper purpose;

g. Representations that the rebates, fees, and other monies were intended to benefit health benefit providers, plan members and/or the general public;

h. Representations that the "preferred" formulary status of the Insulin Drugs reflected the drugs' safety, efficacy, or cost-effectiveness, as determined by the PBM Defendants' formulary committees;

i. Omissions of fact that the PBM Defendants used their position regarding the development, management, and administration for their own financial benefit and in contravention of the economic interests of their health benefit provider clients (and plan members);

j. Omissions of fact and concealment of the fact that the Insulin Drugs would have been placed in "preferred" formulary positions absent the bribes;

k. Publishing artificially inflated prices; and

l. Representing that the administrative fees paid by the Manufacturer Defendants to the PBM Defendants were, in words or substance, for "for administrative services performed by Pharmacy Benefit Manager in relation to the processing, invoicing for or collection of any Rebates" when those services are already performed by the PBM Defendants and paid for by the TPP clients of the PBM Defendants pursuant to the

contracts between the TPP clients and the PBM Defendants that represent them.

205. The Manufacturer Defendants alone could not have accomplished the purposes of the Insulin Pricing Enterprises without the PBM Defendants. For the Manufacturer Defendants to profit from the scheme, the PBM Defendants needed to convince health benefit providers to select their formularies, on which the Insulin Drugs were given favorable treatment. And the PBM Defendants did so through misrepresentations: they told clients, potential clients, and investors that they secured lower prices. Instead, the Manufacturer Defendants inflated list prices and funded the bribes and kickbacks in exchange for favorable placement on the PBM Defendants' formularies, which resulted in increased drug costs. Without these misrepresentations, no Insulin Pricing Enterprise could have achieved its common purpose.

206. The impacts of the Insulin Pricing Enterprises are still in place as a result of the Manufacturer Defendants' inflated list prices. As described herein, the bribes and kickbacks are an essential part of the Insulin Pricing Enterprises and are embedded in the ongoing Insulin Drugs' prices. This conduct constitutes a threat of continued criminal activity.

207. The foregoing evidences that the Manufacturer Defendants and the PBM Defendants were each willing participants in the Insulin Pricing Enterprises,

had a common unlawful and fraudulent purpose and interest in the objective of the scheme, and functioned within a structure designed to effectuate the Enterprises' purposes, *i.e.*, to increase profits for both the Manufacturer Defendants and the PBM Defendants through price increases, bribes, and kickbacks to the PBM Defendants, and maintain continued formulary status without price reductions from the Manufacturer Defendants, preserving and increasing the Manufacturer Defendants' profits.

A. Conduct of the RICO Enterprises' Affairs

208. During the Class Period, each of the Manufacturer Defendants has exerted control over each Insulin Pricing Enterprise with which it is associated and, in violation of Section 1962(c) of RICO, each Manufacturer Defendant has conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly, as follows:

a. Controlling the list prices for the Insulin Drugs, which determine the amount of rebates, administrative fees, and other monies each of the PBM Defendants realizes in compensation in exchange for formulary placement;

b. Controlling list prices for the Insulin Drugs and increases thereof that it publicly reports and purports to explain;

c. Controlling the creation and distribution of marketing, sales, and other materials used to inform each of the PBM Defendants of the profit potential of the Insulin Drugs;

d. Promoting the scheme through the U.S. mail, through interstate wire facilities, and through direct contacts with the PBM Defendants;

e. Providing bribes and kickbacks, falsely and misleadingly labeled as rebates or administrative fees, to induce the PBM Defendants to place the Insulin Drugs in a favorable position on the PBM's formulary;

f. Intending that the PBM Defendants would (and did) distribute, through the U.S. mail and interstate wire facilities, promotional and other materials which claimed that rebates lowered drug costs for health benefit provider clients and their plan members;

g. Publishing and announcing collusive, artificially inflated list price increases and the reasons therefore, but concealing that the increases were to fund the bribes and kickbacks to the PBM Defendants to secure favorable, preferred, or exclusive formulary placement;

h. Representing that the administrative fees paid by the Manufacturer Defendants to the PBM Defendants were, in words or substance, for "for administrative services performed by Pharmacy Benefit Manager in relation to the processing, invoicing for or collection of any Rebates"

when those services are already performed by the PBM Defendants and paid for by the TPP clients of the PBM Defendants pursuant to the contracts between the TPP clients and the PBM Defendants that represent them; and

i. Taking steps to conceal the extent to which the Manufacturer Defendants' payments to the PBM Defendants were retained by the PBM Defendants, which, among other things, (1) involved the inclusion of notice provisions in the contracts between the PBM Defendants and their clients for the purpose of foreclosing discovery of those contracts by arguing that discovery of those contracts would be too burdensome, (2) calculating and invoicing rebate payments by hand rather than by using their sophisticated and powerful information processing systems, and (3) forming and utilizing Rebate Aggregators with stringent requirements for TPP Clients to conduct in person reviews of accounting summaries.

209. Further, during the Class Period, each PBM Defendant has exerted control over each Insulin Pricing Enterprise with which it is associated and, in violation of Section 1962(c) of RICO, has conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, by, among other things as described herein:

a. Soliciting and/or obtaining bribes and kickbacks (falsely labeled as rebates, so-called administrative fees, and/or other monies) in exchange for placing the Insulin Drugs in a favorable, preferred, or exclusive position on the PBM's formularies; and

b. Publishing, distributing, and disseminating materials and information concerning the Insulin Drugs' list prices, net prices, and/or the purpose of rebates and fees to perpetuate and conceal the scheme.

210. In addition, CVS Caremark and Express Scripts specifically have conducted or participated in the conduct of the affairs of their association-in-fact RICO enterprises, by, among other things:

a. Misrepresenting and/or concealing from Local 1, Class members, health benefit providers, plan members, and the public the existence, amount, and purpose of the rebates, administrative fees, and/or other monies from the Manufacturer Defendants; and

b. Misrepresenting and/or concealing from Local 1, Class members, health benefit providers, plan members, and the public the effect of the rebates, so-called administrative fees, and/or other monies from the Manufacturer Defendants on the Insulin Drug list prices.

B. Defendants' Pattern of Racketeering Activity

211. Each of the Defendants has conducted and participated in the affairs of the respective Insulin Pricing Enterprises through a pattern of racketeering activity under 18 U.S.C. § 1961, and committed the following violations outlined below knowingly and with the intent to advance the scheme.

212. Defendants' pattern of racketeering has involved thousands, if not hundreds of thousands, of racketeering acts, and has occurred over the period from 2009 through the present.

213. All of Defendants' racketeering activities amounted to a common course of conduct, with a similar pattern and purposes. The payments of bribes and kickbacks, misrepresentations and omissions, and separate uses of the U.S. mail and/or interstate wires by Defendants and each Insulin Pricing Enterprise in connection with the illegal schemes were substantially related, had similar intended purposes, involved similar participants and methods of execution, and had similar results affecting similar victims. The racketeering activity constitutes a threat of continuing criminal activity.

214. Defendants have committed the following predicate acts, all constituting racketeering activity under 18 U.S.C. § 1961.

215. The above-described conduct by Defendants through their respective Insulin Pricing Enterprises constitute commercial bribery chargeable as a crime

under State law and punishable by imprisonment for more than one year and hence constitute RICO predicate acts pursuant to 18 U.S.C. §1961(1)(A).

1. Unlawful Kickbacks for Benefit Plan Services in Violation of 18 U.S.C. § 1954

216. As hereinbefore alleged, more than 54 percent of the individuals in this country receive prescription drug benefits through their employers pursuant to an employee welfare benefit plan as defined in 29 U.S.C. §1002(1).

217. As hereinbefore alleged, the PBM Defendants are legal persons who provide benefit plan services to most of these employee benefit plans.

218. In direct violation of 18 U.S.C § 1954, the Manufacturer Defendants paid and the PBM Defendants received Insulin kickbacks with the intention of influencing the choice of analog insulin to include in the benefit plan formularies that determine whether and to what extent a particular insulin is available to patients whose prescription drug benefits are provided, in whole or in part, pursuant to an employee welfare benefit plan, all in direct violation of 18 U.S.C. §1954, and therefore comprising racketeering activity by the Insulin Pricing Enterprises under 18 U.S.C § 1961(1)(B).

2. Unlawful Bribery in Violation of 18 U.S.C. §§ 1952, 666(a), 666(b)

219. For each year during the Class Period, each of the Defendants received in excess of $10,000 in funds from federal health care programs such as Medicare, Medicaid, and CHAMPVA.

220. For each year during the Class Period, each of the Manufacturer Defendants paid and each of the PBM Defendants received in excess of $5,000 in "rebates," "administrative fees," and other kickbacks from the sale of the Insulin Drugs.

221. Such "rebates," "administrative fees," and other kickbacks were corruptly solicited, demanded, paid, and accepted for the purpose of influencing the PBM Defendants to cause the Insulin Drugs to be placed on the preferred drug formularies maintained on behalf of such federally funded programs and to reward the Manufacturer Defendants for doing so.

222. Given that, the Insulin kickback scheme adopted and implemented by the Insulin Pricing Enterprises constitute a violation of 18 U.S.C. §§ 1952, 666(a), 666(b) and, as such, comprises racketeering activity under 18 U.S.C. § 1961(1)(B).

3. Violations of the AKS Comprising Racketeering Activity under 18 U.S.C. § 1957

223. The commercial bribes and kickbacks paid by the Manufacturer Defendants to the PBM Defendants in connection with prescriptions funded in whole

or in part by federal health care programs such as Medicare, Medicaid, and CHAMPVA totaled well over $10,000 per year and were deposited in financial institutions that included federally insured banks.

224. The commercial bribes and kickbacks paid by the Manufacturer Defendants to the PBM Defendants in connection with prescriptions funded in whole or in part by federal health care program such as Medicare, Medicaid, and CHAMPVA were paid and received with the corrupt and unlawful intention of purchasing, and in fact purchasing, formulary placement for the Insulin Drugs and, as such, constituted ongoing violations of the AKS.

225. The PBM Defendants knew that the payments that they received from the Manufacturer Defendants were derived from payments solicited and received in violation of the AKS and such payments were, in fact, derived from kickback transactions in violation of the AKS.

226. The AKS is a criminal prohibition against payments made purposefully to induce or reward the referral or generation of federal health care business. The Act criminalizes a drug company's offer or payment of anything of value in return for a PBM's placing that manufacturer's drug in a favorable formulary position with respect to, in whole or part, a federal health care program. This includes a drug manufacturer's offer or payment to a PBM respecting private, nonfederal business that implicitly or explicitly requires that the PBM place the manufacturer's drug in

a favorable position with respect to a federal health care program. The AKS extends not just to a drug manufacturer's payment, but also to the solicitation or acceptance of remuneration by PBMs.

227. The OIG and the Secretary of HHS have long warned that "[l]ump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic and should be carefully scrutinized." 68 F.R. 23731, at 23736 (2003).

228. The purported rebates and fees afforded to the PBM Defendants by the Manufacturer Defendants do not fall within the safe harbor provision because they are not pure "rebates" or fees alone. As stated, they are accompanied by the quid pro quo of getting preferred formulary treatment. Additionally, these supposed "rebates" do not reduce the Manufacturer Defendants' selling prices as they increased prices to make up for an increased "rebate."

229. The conduct of each of the Insulin Pricing Enterprises, as described herein, amounts to a violation of 18 U.S.C. § 1957 and is racketeering activity as defined in 18 U.S.C. 1961(1)(B).

4. Unlawful Bribery Under the Travel Act and AKS in Violation of 18 U.S.C. § 1952(a) and 42 U.S.C. § 1320a-7b(b)(2)

230. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each of the Insulin Pricing Enterprises have, in violation of 18 U.S.C. § 1952(a), used U.S. mail and wire facilities in interstate commerce to intentionally promote,

manage, establish, carry on, and facilitate the unlawful activity of bribery under the laws of the United States and the laws of the state where committed. *See* 18 U.S.C. § 1952(b)(2).

231. Specifically, as alleged immediately above, through the U.S. mail and wire facilities in interstate commerce in violation of the AKS, each Manufacturer Defendant paid bribes to each of the PBM Defendants, which the PBM Defendants solicited and/or accepted, with the intention of purchasing, and in fact purchasing, formulary placement for the Insulin Drugs for which payment may be made in whole or in part under one or more Federal health care programs.

5. Mail and Wire Fraud in Violation of 18 U.S.C. §§ 1341, 1343.

232. During the Class Period, each of the Insulin Pricing Enterprises engaged in and affected interstate commerce because they engaged in the following activities across state boundaries: the sale, promotion, recommendation for purchase, and/or administration of prescriptions of the Insulin Drugs; the setting of the prices of the Insulin Drugs and price increase announcements in connection therewith; the negotiation of formulary placement, rebate, and other contracts; the transmission and/or receipt of sales and marketing literature; and/or the transmission and/or receipt of invoices, statements, and payments related to the purchase, use, and/or administration of the Insulin Drugs. During the Class Period, the Insulin Pricing

Enterprises participated in the sale, promotion, recommendation for purchase, and administration of prescriptions for the Insulin Drugs throughout the United States.

233. During the Class Period, Defendants' illegal conduct and wrongful practices in furtherance of the unlawful aims of the Insulin Pricing Enterprises were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mail and interstate wire facilities.

234. The nature and pervasiveness of Defendants' scheme, which was concertedly orchestrated out of the respective corporate headquarters of the Manufacturer Defendants and the PBM Defendants, necessarily required those Manufacturer Defendants' headquarters to communicate directly and frequently by the U.S. mail and by interstate wire facilities with the headquarters of the PBM Defendants, and vice versa.

235. Most of the precise dates of Defendants' uses of the U.S. mail and interstate wire facilities (and corresponding RICO predicate acts as outlined herein) have been hidden and cannot be alleged without access to these Defendants' books and records. Indeed, an essential part of the successful operation of the bribery and kickback scheme alleged herein depended upon secrecy. Defendants took deliberate steps to conceal their wrongdoing. Local 1 can nevertheless generally describe the occasions on which the RICO predicate acts of unlawful payment of bribes and

kickbacks, mail fraud, and wire fraud occurred, and how those acts were in furtherance of the list price inflation and rebate bribery and kickback scheme.

236. Defendants' use of the U.S. mail and interstate wire facilities to perpetrate the scheme involved thousands of communications throughout the Class Period including, *inter alia*:

a. Publication of artificially inflated prices and publication of marketing materials about the collusively set artificial list prices for the Insulin Drugs, which the Manufacturer Defendants sent to the PBM Defendants and others located across the country;

b. Written and oral representations about the Insulin Drug list prices that the Manufacturer Defendants made at least annually and, in many cases, several times during a single year;

c. Thousands of written and oral communications discussing, negotiating, conditioning, and confirming the placement of the Insulin Drugs on a particular PBM Defendant's formulary;

d. Written and oral representations to conceal the true reasons for the Insulin Drugs' list price increases and to conceal the scheme;

e. Written communications, including checks, wires, and/or other payment mechanisms, relating to rebates, bribes, kickbacks, or other financial inducements paid by each of the Manufacturer Defendants to

each of the PBM Defendants to induce them to place the Insulin Drugs on the PBM Defendants' formularies in a favorable position;

f. Written and oral communications with U.S. government agencies and health benefit providers that fraudulently misrepresented the reasons for list price increases, or that were intended to deter investigations into the true nature of the list price increases, or to forestall changes to reimbursement based on something other than list prices;

g. Written and oral communications with direct purchasers, health benefit providers and patients concerning list prices and the reasons for increases thereof;

h. Written and oral communications by the PBM Defendants and/or the Manufacturer Defendants with health benefit providers, and patients concerning list prices and/or the reasons for increases thereof;

i. As to Caremark CVS and Express Scripts, sending invoices and requests for payment to Local 1 and Class members using the mail and wires;

j. Receipts and payments of money on tens of thousands of occasions through the U.S. mail and interstate wire facilities, constituting the wrongful proceeds of the list price inflation and bribery scheme, including Local 1 and Class members; and

k. In addition to the RICO predicate acts, Defendants' corporate headquarters have communicated through use of the U.S. mail and by interstate wire facilities with their own various local headquarters or divisions, in furtherance of the list price inflation and bribery scheme.

237. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Defendants have, in violation of 18 U.S.C. § 1341, used the U.S. mail in conducting a scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises.

238. Specifically, as outlined above, each Insulin Drug has been promoted through the mail, thereby announcing to health benefits providers, including Local 1 and Class members each Manufacturer Defendant's artificially inflated list price increases but omitting the material fact that the reason for the increased list prices was to fund, increase, and/or recoup each Manufacturer Defendant's bribes and kickbacks to CVS Caremark and Express Scripts to secure formulary placement. Moreover, Defendants have falsely and misleadingly called the bribes and kickbacks to the PBM Defendants "rebates" — which have been publicly represented as lowering drug costs — when they are, in fact, bribes and kickbacks for formulary placement, which enabled each Manufacturer Defendant to sell the Insulin Drugs at inflated prices.

239. Moreover, the PBM Defendants falsely and fraudulently represented to the TPP clients of the PBM Defendants, to Class Members and to the public through the U.S. mail and interstate wires that the "Administrative Fees" or "Manufacturer Administrative Fees" charged by the PBM Defendants to the Manufacturer Defendants as a condition to formulary placement of the Insulin Drugs were, in words or substance, "for administrative services performed by Pharmacy Benefit Manager in relation to the processing, invoicing for or collection of any Rebates" when those services are already performed by the PBM Defendants and paid for by the TPP clients of the PBM Defendants pursuant to the contract between the TPP clients and the PBM Defendants that represent them.

240. Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mail in furtherance of their schemes.

241. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Defendants have, in violation of 18 U.S.C. § 1343, transmitted or caused to be transmitted by means of wire, radio, or television, communication in interstate commerce, in conducting a scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises. Specifically, as outlined above, each of the Insulin Drugs has been promoted through electronic means, thereby announcing to Local 1 and Class members, health benefit

providers, patients, and the public its collusive and artificially high list price increases, but omitting the material fact that the reason for the increased list prices was to fund, increase, and/or recoup each Manufacturer Defendant's bribes and kickbacks to each of the PBM Defendants to secure formulary placement. Moreover, Defendants have falsely and misleadingly called the bribes and kickbacks to the PBM Defendants "rebates" — which have been publicly represented as lowering drug costs — when they are, in fact, bribes and kickbacks for formulary placement, which enabled Defendants to sell the Insulin Drugs at inflated prices.

242. Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of interstate wires in furtherance of their schemes.

C. Harm Caused by Defendants' Bribery, Kickback, and Fraud Scheme

243. Defendants' violations of federal law and their pattern of racketeering activity have directly and proximately caused Local 1 to be injured in its business or property by overpaying for the Insulin Drugs. Local 1 directly purchased the Insulin Drugs from the PBM Defendants Caremark CVS and Express Scripts, and thus was directly and immediately harmed by Defendants' schemes. Defendants intended and foresaw that Local 1 and Class members would pay substantial overcharges due to Defendants' pattern of racketeering activity.

244. During the Class Period, the Manufacturer Defendants paid bribes and kickbacks to the PBM Defendants in exchange for preferred formulary placement in order to maximize their sales and profits. To fund these bribes and kickbacks, with the knowledge and agreement of the PBM Defendants, the Manufacturer Defendants colluded to increase the list prices of the Insulin Drugs, which caused the prices Local 1 and Class members paid to be artificially high.

245. Though the PBM Defendants could have used their control over the development, management, and administration of the formularies and prescription drug programs that their health benefit providers relied upon to drive down the prices for insulin by forcing the Manufacturer Defendants to lower their list prices, the PBM Defendants instead leveraged their position to obtain the Manufacturer Defendants' bribes and kickbacks for their own financial benefit and contrary to the economic interests of their health benefit provider clients and plan members.

246. Rather than lower their prices to gain market share via formulary inclusion, the Manufacturer Defendants instead engaged in a scheme with the PBM Defendants to corrupt the supply chain by artificially inflating list prices in exchange for preferred formulary placement, shifting the cost of the bribes and kickbacks to direct purchasers of the Insulin Drugs such as Local 1 and Class members and sharing those financial benefits with the PBM Defendants.

247. Absent the payment of bribes and kickbacks, and their achievement through the Insulin Drugs' list price increases, the Manufacturer Defendants would have been forced to compete for preferred formulary placement through lower prices, as they would in a legitimate market. As the gatekeepers in the supply chain, the PBM Defendants could and would have used formulary placement (or exclusion) to penalize manufacturers who raised prices as the Manufacturer Defendants did here, rather than perversely rewarding manufacturers who raised prices and inducing them to do so with favorable formulary placement.

248. But for the payment of bribes and kickbacks, and their achievement through list price increases, the Insulin Drugs would have had a lower list price, and Local 1 and Class members would have paid less for the Insulin Drugs. Local 1 and Class members have overpaid hundreds of millions of dollars for the Insulin Drugs purchased directly from the Defendants.

249. Defendants' racketeering activity directly and proximately caused Local 1 and Class members' injuries because Local 1 and Class members purchased the Insulin Drugs directly from Defendants. Further, given that Local 1 and Class members were and are the most direct and immediate victims of the unlawful and fraudulent schemes, Local 1 and Class members are best situated to vindicate the law and seek recovery for the economic harm caused by Defendants based on the

substantial overcharges for the Insulin Drugs, which only Local 1 and Class members paid.

250. By virtue of these violations of 18 U.S.C. § 1962(c), pursuant to 18 U.S.C. § 1964(c), the Manufacturer Defendants and PBM Defendants CVS Caremark and Express Scripts are, respectively, jointly and severally liable to Local 1 and Class members for three times the overcharges that Local 1 and Class members have paid, plus the costs of bringing this suit, including reasonable attorneys' fees.

COUNT THREE
CONSPIRACY IN VIOLATION OF 18 U.S.C. § 1962(d) (AS TO ALL DEFENDANTS)

251. Local 1 hereby incorporates by reference the allegations contained in the paragraphs 1–250 of this Class Action Complaint.

252. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

253. Each Manufacturer Defendant and each of the PBM Defendants has violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of the respective conspiracies has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the § 1962(c) Manufacturer-PBM Insulin Pricing Enterprises described previously through a pattern of racketeering activity.

254. As set forth in detail above, Defendants have engaged in numerous overt and predicate unlawful and fraudulent acts, constituting a pattern of racketeering activity, in furtherance of the conspiracy. Defendants intended to engage in the schemes, resulting in Plaintiffs and Class members paying substantial overcharges for the Insulin Drugs. Defendants knew that their predicate acts were part of a pattern of racketeering activity and agreed to the commission of those acts to further the schemes outlined herein.

255. The nature of Defendants' acts, material misrepresentations, and omissions in furtherance of the conspiracy, as set forth in detail above, gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but that they were aware that their ongoing unlawful and fraudulent acts have been and are part of an overall pattern of racketeering activity.

256. Defendants have engaged (and continue to engage) in the commission of overt acts in furtherance of the Manufacturer-PBM Insulin Pricing Enterprise schemes, including the following unlawful racketeering predicate acts (as outlined in detail above):

a. Multiple instances of unlawful bribery and kickbacks in violation of 18 U.S.C. §§ 666(a), 666(b), 1952, 1954, 1957, 1961(1), and 42 U.S.C. 1320a-7b(b)(2);

b. Multiple instances of mail fraud in violation of 18 U.S.C. § 1341; and

c. Multiple instances of wire fraud in violation of 18 U.S.C. § 1343.

257. Defendants' violations of the above federal laws and the effects thereof outlined in detail above are continuing and will continue. As a direct and proximate result of these violations, Plaintiffs and Class members have been injured in their business and property; Plaintiffs and Class members have made hundreds of millions of dollars in overpayments for the Insulin Drugs purchased directly from the Manufacturer Defendants that they would not have paid but for Defendants' conspiracies to violate 18 U.S.C. § 1962(c).

258. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are, respectively, jointly and severally liable to Plaintiffs and Class members for three times the damages Plaintiffs and Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

XI. Prayer for Relief

WHEREFORE, Plaintiffs and Class members pray for relief as set forth below:

A. Certification of the Class pursuant to Federal Rule of Civil Procedure 23, appointment of Local 1 Health Fund and Local 1 Health Fund Plan as class representatives, and appointment of Plaintiffs' counsel as Class Counsel;

B. A judgment against Defendants, jointly and severally, for the damages sustained by Plaintiffs and the Class members defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;

C. Pre-judgment and post-judgment interest at the highest legal rate;

D. The costs of this suit, including reasonable attorneys' fees and expenses; and

E. Such other and further relief as the Court deems just and proper.

XII. Jury Demand

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs, individually and on behalf of all others similarly situated, hereby request a jury trial on all claims so triable.

Dated: October 13, 2023

Respectfully submitted,

/s/Matthew F. Gately

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